C: 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1302

RIN 0970-AC90

Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment (IFC) adds new provisions to the Head Start Program Performance Standards to mitigate the spread of the coronavirus disease 2019 (COVID-19) in Head Start programs. This IFC requires effective upon publication, universal masking for all individuals two years of age and older, with some noted exceptions, and all Head Start staff, contractors whose activities involve contact with or providing direct services to children and families, and volunteers working in classrooms or directly with children to be vaccinated forCOVID-19 by January 31, 2022.

DATES: *Effective date*: This IFC is effective on [INSERT DATE OF PUBLICATION].

Compliance date: The compliance date for the mask requirement is the date of publication of the rule, November 30, 2021. The compliance date for the vaccine requirement is January 31, 2022. For more information, *see* **SUPPLEMENTARY INFORMATION**.

Comment date: To be assured consideration, comments on this interim final rule must be received on or before [INSERT 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by [docket number and/or RIN number], by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Office of Head Start, Attention: Director of Policy and Planning, 330 C Street, SW, 4th Floor, Washington, DC 20201.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. All comments received will be posted without change to http://www.regulations.gov, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Colleen Rathgeb, OHS, at HeadStart@eclkc.info or 1-866-763-6481. Deaf and hearing-impaired individuals may call the Federal Dual Party Relay Service at 1-800-877-8339 between 8 a.m. and 7 p.m. Eastern Standard Time.

SUPPLEMENTARY INFORMATION: The compliance date for the vaccine requirement is January 31, 2022. This means staff, certain contractors and volunteers must have their second dose in a two-dose series, or first dose in a single-dose by January 31, 2022. Full vaccination requires 14 days after a two-dose series such as Pfizer or Moderna or 14 days after a single-dose series like Johnson & Johnson, but for purposes of this regulation, staff, certain contracts and volunteers will meet the requirement even if they have not yet completed the 14-day waiting period required for full vaccination. This timing flexibility applies only to the initial implementation of this IFC and has no bearing on ongoing compliance.

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I. Tribal Consultation Statement

ACF conducts an average of five tribal consultations each year for tribes operating Head Start and Early Head Start. The consultations are held in four geographic areas across the country: Southwest, Northwest, Midwest (Northern and Southern), and East. The consultations are often held in conjunction with other tribal meetings or conferences, to ensure the opportunity for most of the 150 tribes that operate Head Start and Early Head Start programs to attend and voice their concerns regarding service delivery. We complete a report after each consultation, and then we compile a final report that summarizes the consultations. We submit the report to the Secretary of Health and

Human Services (the Secretary) at the end of the year. We invite public comment on this IFC if there are concerns specific to Native communities and programs.

II. Statutory Authority

ACF publishes this interim final rule under the authority granted to the Secretary by sections 641A(a)(1)(C), (D) and (E) of the Head Start Act, 42 U.S.C. 9836a(a)(1)(C)–(E)), (D) and (,),, as amended by the Improving Head Start for School Readiness Act of 2007 (Pub. L. 110-134).

III. Executive Summary

A. Purpose of the Interim Final Rule

SARS-CoV-2, the infectious agent that causes COVID-19, is considered to be mainly transmissible through exposure to respiratory droplets when a person is in close contact with someone who has COVID-19. Correct and consistent facemask use has been critical in reducing the risk of droplet transmission of SARS-CoV-2.[1,2]Vaccination is the most important measure for reducing risk for SARS-CoV-2 transmission and in avoiding severe illness, hospitalization, and death.[3]

Four primary variants of SARS-CoV-2 have emerged to date. Of these, the Delta variant has been of particular concern as it causes more infections and spreads faster than other variants.[4] While the Delta variant has increased levels of transmissibility, COVID-19 vaccination remains highly effective against hospitalization and death. Although there are cases of SARS-CoV-2 infections among vaccinated individuals,[5] fully vaccinated adults were six times less likely to become infected, twelve times less likely to be

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[1] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html
[2] https://www.osha.gov/coronavirus/safework
[3] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

[4] Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." August 26, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html
[5] Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021 | MMWR

hospitalized and eleven times less likely to die from COVID-19 compared to unvaccinated adults according to data from August 2021.[6,7] While studies are still ongoing, preliminary data suggest that vaccinated persons infected with the Delta variant are potentially less infectious, and infectious for shorter periods of time compared to infected unvaccinated persons.[8,9,10,11,12,13]

The purpose of this IFC is to protect the health and safety of Head Start staff, children, and families and to mitigate the spread of SARS-CoV-2 in Head Start programs. It requires: (1) universal masking for all individuals two years of age and older, with some noted exceptions, effective immediately upon publication of this rule), (2) vaccination for COVID-19 by January 31, 2022, with some noted exemptions, for all Head Start program staff, inclusive of Head Start, Early Head Start, and Early Head Start-Child Care Partnerships, certain contractors, and volunteers in classrooms or working directly with children (hereafter referred to as "Head Start staff"), and (3) for those granted an exemption to the requirement specified in (2), at least weekly testing for current SARS-CoV-2 infection. The requirements in this IFC will reduce the risk of transmission of SARS-CoV-2 in classrooms, which will protect the health and safety of children, reduce closures of Head Start programs, which can cause hardship for families,

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[6] https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status MMWR Morb Mortal Wkly Rep 2021;70:1255–1260. DOI: http://dx.doi.org/10.15585/mmwr.mm7036e2
[7] https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

[8] Chia PY, Ong SWX, Chiew C, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. medRxiv. 2021;https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1
[9] Shamier MC, Tostmann A, Bogers S. Virological characteristics of SARS-CoV-2 vaccine breakthrough infections in health care workers. medRxiv. 2021;https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1
[10] Kang M, Xin H, Yuan J. Transmission dynamics and epidemiological characteristics of Delta variant infections in China. medRxiv. 2021;https://www.medrxiv.org/content/10.1101/2021.08.12.21261991v1
[11]Ong SWX, Chiew CJ, Ang LW, et al. Clinical and Virological Features of SARS-CoV-2 Variants of Concern: A Retrospective Cohort Study Comparing B.1.1.7 (Alpha), B.1.315 (Beta), and B.1.617.2 (Delta). Preprints with The Lancet. 2021;https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3861566
[12] Mlcochova P KS, Dhar MS, et al. . SARS-CoV-2 B.1.617.2 Delta variant emergence and vaccine breakthrough. Research Square. 2021 https://www.researchsquare.com/article/rs-637724/v1
[13] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

and support the Administration's priority of sustained in-person early care and education that is safe for children—with all of its known benefits to children and families.[14]

Greater understanding about the spread ofSARS-CoV-2, the increased risk to certain populations, the benefits of masking, and the safety and efficacy of vaccines demonstrates the need for widespread masking and vaccination to reduce COVID-19 and its impacts. Although COVID-19 cases had begun to decline in parts of the country following the most recent COVID-19 surge, data indicate cases are beginning to rise in other parts—particular northern states where the weather has begun to turn colder ,[15] and the future trajectory of the pandemic is unclear. The Delta variant is currently the predominant variant in the United States and has resulted in greater rates of cases and hospitalizations among children than from other variants.[16,17,18] Furthermore, there is potential for the rapid and unexpected development and spread of additional new and more transmissible variants. Experience with the Delta variant suggests that we must take adequate steps to prevent transmission and protect the workforce and children to avoid serious harm.[19] It is critical that all Head Start staff get fully vaccinated for

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[14] Barr, A. C., & Gibbs, C. (2019). *Breaking the Cycle? Intergenerational Effects of an Anti-Poverty Program in Early Childhood*. EdWorkingPaper: 19-141. Retrieved from Annenberg Institute at Brown University, https://edworkingpapers.com/sites/default/files/ai19-141.pdf.; Bauer, L., & Schanzenbach, D. W. (2016). *The Long-Term Impact of the Head Start Program*. Washington, DC: The Brookings Institute. Retrieved from: https://www.hamiltonproject.org/assets/files/long_term_impact_of_head_start_program.pdf.; Ludwig, J., & Phillips, D. (2007). The Benefits and Costs of Head Start. *Social Policy Report, Vol. 21*(3), Society for Research in Child Development. Retrieved from: https://files.eric.ed.gov/fulltext/ED521701.pdf.; Garcia, J. L., Heckman, J. J., Leaf, D. E., & Prados M. J. (2019). Quantifying the Life-cycle Benefits of a Prototypical Early Childhood Program. National Bureau of Economic Research Working Paper No. 23479. Cambridge, MA: NBER. Retrieved from: https://heckmanequation.org/www/assets/2017/01/w23479.pdf.; Yoshikawa, H., Weiland, C., Brooks-Gunn, J., Burchinal, M. R., Espinosa, L. M., Gormley, W. T., Ludwig, J., Magnuson, K. A., Phillips, D., & Zaslow, M. (2013). *Investing in Our Future: The Evidence Base on Preschool Education*. Society for Research in Child Development and Foundation for Child Development. Retrieved from: http://www.fcd-us.org/assets/2013/10/Evidence20Base20on20Preschool20Education20FINAL.pdf

[15] https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

[16] Delahoy, M., et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents -COVID-Net, 14 States, March 1, 2020 – August 14, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e2.htm

[17] Siegel DA, Reses HE, Cool AJ, et al. Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021.

[18] https://covid.cdc.gov/covid-data-tracker/#demographicsovertime

[19] Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." August 26, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html

COVID-19 and consistently wear masks to protect children, staff, and families from exposure to SARS-CoV-2 and to reduce the risk of transmission to families of Head Start children and staff who may be at risk for increased morbidity and mortality from COVID-19.

This IFC adds provisions to the Head Start Program Performance Standards to impose three requirements:

(1) Universal masking, with some noted exceptions, for all individuals two years of age and older when there are two or more individuals in a vehicle owned, leased, or arranged by the Head Start program; when they are indoors in a setting where Head Start services are provided; and, for those not fully vaccinated, outdoors in crowded settings or during activities that involve close contact with other people. This requirement is effective immediately.

(2) Vaccination for COVID-19 for Head Start program staff, certain contractors and volunteers by January 31, 2021.

(3) For those granted an exemption to the requirement specified in (2), at least weekly testing for current SARS-CoV-2 infection.

Being fully vaccinated for COVID-19 and using a mask are two of the most effective mitigation strategies available to reduce transmission ofSARS-CoV-2.[20] Additionally, including a regular SARS-CoV-2 testing requirement for those approved for an exemption from the vaccination requirement is necessary to identify infected employees and separate them from the workplace to prevent transmission and to facilitate early medical intervention, when appropriate. Fully vaccinated staff are at much lower risk of infection and therefore, pose lower transmission risk to the young unvaccinated children

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[20] Centers for Disease Control and Prevention. "Science Brief: COVID-19 Vaccines and Vaccination." September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.

in their care. The CDC recommends screening testing for current infection of unvaccinated asymptomatic workers as a useful tool to detect SARS-CoV-2 and stop transmission quickly.[21]

B. Interim Final Rule Justification

Section 641A of the Head Start Act authorizes the Secretary to "modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs," including "administrative and financial management standards," "standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) for such agencies, and programs," and "such other standards as the Secretary finds to be appropriate," 42 U.S.C. 9836a§ 9836a(a)(1)(C),(D), (E). In developing these modifications, the Secretary included relevant considerations pursuant to section 641A(a)(2) of the Head Start Act, 42 U.S.C. 9836a(a)(2). The Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA. The Secretary considered the Office of Head Start's past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures. The Secretary finds it necessary and appropriate to set health and safety standards for the condition of Head Start facilities

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[21]Centers for Disease Control. "Overview of Testing for SARS-CoV-2 (COVID-19)" October 22, 2021.
Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

that ensure the reduction in transmission of the SARS-CoV-2 and to avoid severe illness, hospitalization, and death among program participants.

ACF initially chose, among other actions, to allow Head Start programs to decide whether or not to require staff vaccination rather than require vaccination, to provide information on the COVID-19 vaccine through its Early Childhood Learning and Knowledge Center[22], the website used to share guidance and information with Head Start grant recipients, and to emphasize that grant recipients can use COVID-19 response funds and American Rescue Plan funds to support staff in getting the COVID-19 vaccine. However, despite all of these efforts, uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families. This is particularly true given the advent of the Delta variant and the potential for new variants and as programs continue to return to fully in-person services as the Office of Head Start expects in January 2022. The Office of Head Start (OHS) issued guidance to programs on May 20, 2021 outlining its expectations for programs in the 2021-2022 program year. This guidance prepared programs for the resumption of in-person services and informed programs that they should build toward full enrollment and provide comprehensive services for all enrolled children as soon as possible. It noted that beginning January 2022, OHS intends to reinstate pre-pandemic practices for tracking and monitoring enrollment. OHS will also resume evaluating which programs enter into the Full Enrollment Initiative in January 2022, which is a process by which OHS identifies programs that are not serving their full funded enrollment. This guidance followed a period since the onset of the pandemic of greater flexibility for programs with requirements related to enrollment, service duration,

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[22] Office of Head Start. "OHS COVID-19 Updates." Available at: https://eclkc.ohs.acf.hhs.gov/about-us/coronavirus/ohs-covid-19-updates

virtual/remote delivery of services, among others. These flexibilities were critical to programs' ability to continue providing services to children and families and to adapt services based on the changing health conditions in their communities during unprecedented times. As programs prepare for fully in-person services, it is imperative that we create conditions that support the health and safety of children and reduce program closures and service interruptions. The universal masking and vaccination requirements outlined in this IFC are critical to this effort.

The U.S. Centers for Disease Control and Prevention (CDC) issued guidance July 27, 2021.[23] The CDC stated that the rationale for this guidance was twofold: (1) an alarming rise in COVID-19 cases and hospitalization rates around the country—a reversal in what had been a steady decline since January 2021[24] and (2) new data showing the Delta variant to be highly transmissible.[25] A study covering the period from June to mid-August 2021 showed that weekly COVID-19 associated hospitalization rates among children and adolescents rose nearly five-fold during the late June to mid-August 2021 period, which coincided with increased circulation of the Delta variant.[26] In this same study, hospitalization rates were 10 times higher among unvaccinated than fully vaccinated adolescents. A separate study conducted in the United Kingdom showed that vaccination effectively reduces the risk of Delta variant infection[27] but that "vaccination

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[23] *Centers for Disease Control and Prevention. "Science Brief: COVID-19 Vaccines and Vaccination." September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.*

[24] Centers for Disease Control and Prevention. "COVID Data Tracker." Available at: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network

[25] Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep. ePub: 30 July 2021; https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

[26] Delahoy MJ, Ujamaa D, Whitaker M, et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents — COVID-NET, 14 States, March 1, 2020–August 14, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1255–1260. DOI: http://dx.doi.org/10.15585/mmwr.mm7036e2

[27] Singanayagam, AnikaBadhan, Anjna et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext

alone is not sufficient to prevent all transmission of the delta variant in the household setting, where exposure is close and prolonged." The authors recommended nonpharmaceutical interventions, such as mask wearing, as an important complementary approach alongside vaccination to minimize spread of the Delta variant.

On November 10, 2021, the CDC issued updated guidance to early childhood education and child care (ECE) programs.[28] One of the key changes in the guidance is the recommendation for universal indoor masking for ECE programs for everyone aged 2 years and older regardless of vaccination status, with limited exceptions, see section V *Provisions of the Interim Final Rule.* It also notes that ECE program staff can model consistent and correct use for children aged 2 years or older in their care. Vaccinations and masks are key strategies for reducing the transmission of SARS-CoV-2 along with other risk reduction strategies, including staying home if sick; handwashing; improving ventilation; screening and diagnostic testing, cleaning, and disinfecting; keeping physical distance; and cohorting,[29] especially because physical distancing is not always feasible in early childhood settings.[30]

The COVID-19 vaccines are the safest and most effective way to protect individuals and the people with whom they live and work from infection and from severe illness and hospitalization if they contract the virus. Data from August 2021 indicate that when compared with vaccinated adults, those who were not fully vaccinated were 6 times more likely to become infected, 12 times more likely to be hospitalized, and 11 times

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28 Centers for Disease Control. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." November 10, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html

[29] Cohorting refers to placing children and child care providers into distinct groups who stay together throughout an entire day.

[30] Centers for Disease Control and Prevention. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." August 25, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html; https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html

more likely to die of COVID-19.[31,32] In addition to preventing morbidity and mortality associated with COVID-19, currently available vaccines also demonstrate effectiveness against asymptomatic SARS-CoV-2 infection. A study of the period from December 14, 2020 to August 14, 2021, found that full vaccination for COVID-19 was 80 percent effective in preventing SARS-CoV-2 infection among health care workers.[33] While the scientific evidence for transmissibility of breakthrough cases (i.e., cases in fully vaccinated individuals) is still developing, fully vaccinated individuals are less likely to spread COVID-19 because they are less likely to become infected in the first place. Studies have shown that vaccinations reduce the risk of COVID-19 among unvaccinated close contacts, including children. For example, one study found that vaccination of health care workers was associated with decreased COVID-19 cases among members of their household.[34] Additionally, a study during the early months of the COVID-19 vaccine rollout in Israel found that community vaccination rates were associated with declines in infections among unvaccinated children.[35] Vaccination was also shown to be effective in lowering the risk of severe disease if infected with the Delta variant, which has emerged as a more contagious strain of the SARS-CoV-2 with a higher impact on children than previous variants.[36]

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[31] Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4–July 17, 2021 Early Release / September 10, 2021 / 70

[32] Center for Disease Control and Prevention. "COVID Data Tracker." Available at: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

[33] Fowles, A., Gaglani, M., Groover, K., et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020-August 2021, *Morbidity and Mortality Weekly Report,* August 27, 2021, Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w

[34] Effect of Vaccination on Transmission of SARS-CoV-2. N Engl J Med 2021; 385:1718-1720 DOI: 10.1056/NEJMc2106757

[35] Milman, O., Yelin, I., Aharony, N. et al. Community-level evidence for SARS-CoV-2 vaccine protection of unvaccinated individuals. Nat Med 27, 1367–1369 (2021). https://doi.org/10.1038/s41591-021-01407-5

[36] Centers for Disease Control and Prevention. "COVID Data Tracker. Pediatric Data." Available at: https://covid.cdc.gov/covid-data-tracker/#pediatric-data; Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html; Centers for Disease Control and Prevention. Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021

Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e1.htm?s_cid=mm7036e1_w

Given that children under age 5 years are too young to be vaccinated at this time, requiring masking and vaccination among everyone who is eligible are the best defenses against COVID-19, especially cases arising from the more infectious Delta variant. These measures will also reduce program closures due to SARS-CoV-2 infection. When children or staff test positive for SARS-CoV-2 or have exposure to someone else who has tested positive for SARS-CoV-2, classrooms or entire programs close for a period of days or weeks to allow for test results and quarantining per local health department guidance. Additionally, as discussed later in this IFC, closures impose hardship on Head Start children and families by diminishing the ability to attend Head Start in person. The result is harm to early learning and development. Closures also diminish the ability of parents to work or participate in schooling.

Health and Safety

The Delta variant, which in the summer of 2021 became the predominant SARS-CoV-2 strain in the United States, is more contagious – spreading twice as fast – and results in more cases and hospitalizations for children.[37] The increase in hospitalization is more acute in states with lower vaccination rates. Studies released by CDC found that the rate of hospitalization for children was nearly four times higher in states with the lowest vaccination rates when compared to states with high vaccination rates.[38] Furthermore, hospitalization rates for children in September and October 2021, while lower than other age groups, were elevated relative to other periods during the pandemic.[39] Vaccination remains the best line of defense against COVID-19. Data show

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[37] Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." August 26, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html; https://covid.cdc.gov/covid-data-tracker/#pediatric-data

[38] Siegel DA, Reses HE, Cool AJ, et al. Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1249–1254. DOI: https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e1.htm.

[39] Centers for Disease Control and Prevention. "COVID Tracker Weekly Review." Available at: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

fully vaccinated persons are less likely than unvaccinated persons to become infected with SARS-CoV-2, and infections with the Delta variant in fully vaccinated persons are associated with less severe clinical outcomes.[40] Being fully vaccinated reduces risk of the transmission of SARS-COV-2 from staff to children who are not yet eligible for the vaccine and must be protected to minimize their exposure. Reducing transmission from staff to children and between staff also reduces transmission from children and staff to their family members. Transmission of SARS-CoV-2 in child care settings has been linked to infections and hospitalizations in family members,[41] and some children and staff may return home to family members who are older or have underlying medical conditions that put them at greater risk for COVID-19-related morbidity and mortality. Studies have shown that COVID-19 has disproportionately affected some racial and ethnic minority groups such as Hispanic or Latino, Black or African American, American Indian or Alaskan Native (AIAN), and Native Hawaiian and other Pacific Islander people. [42] It is also estimated that these disparities may have long term implications for these populations: for example, it is estimated that COVID-19 morbidity and mortality impacts can reverse over 10 years of progress in reducing the gaps in life expectancy between Black and White populations.[43] Many families of Head Start children and staff are members of minority communities; 71 percent of families, and 69 percent of staff, self-identify as Hispanic/Latino, Black/African American, American Indian, or Alaska

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[40] Centers for Disease Control and Prevention. "Science Brief: COVID-19 Vaccines and Vaccination." September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.

[41] Lopez AS, Hill M, Antezano J, et al. Transmission Dynamics of COVID-19 Outbreaks Associated with Child Care Facilities — Salt Lake City, Utah, April–July 2020. MMWR Morb Mortal Wkly Rep 2020;69:1319–1323. DOI: http://dx.doi.org/10.15585/mmwr.mm6937e3

[42] Centers for Disease Control and Prevention. "Introduction to COVID-19 Racial and Ethnic Health Disparities." December 10, 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html

[43] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID-19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. https://doi.org/10.1073/pnas.2014746118

Native,[44] who have been shown to be at increased risk of exposure to SARS-CoV-2. Given the disproportionate burden of COVID-19 deaths and lower vaccination rates among racial and ethnic minority groups, requiring vaccination among Head Start staff is not only an issue of personal health, but also promotes public and community health and health equity for children and staff in Head Start programs.[45]A recent CDC study showed that during the period from May 23 to June 12, 2021, 50 percent of the children in a classroom tested positive for SARS-COV-2 infection in a Marin County, California elementary school following exposure to one unvaccinated teacher.[46] This outbreak, which began with an unvaccinated teacher who attended school for two days with symptoms and took off her mask when reading to the class, demonstrates the importance of vaccinating staff members who work closely with young children. The rate of SARS-CoV-2 positivity in the two rows closest to the teacher's desk was 80 percent (8 of 10); in the three back rows, it was 29 percent (4 of 14). Four days after the teacher reported being symptomatic, when the teacher received a positive test, additional cases of COVID-19 were reported among other staff members, students, parents, and siblings connected to the school. In addition to highlighting the importance of vaccination and masking, this study points to the Delta variant's increased transmissibility and potential for rapid spread, especially in unvaccinated populations such as children too young for vaccination.[47]

Additionally, a study covering the period from July 15 to August 31, 2021, that included public K-12 schools in Maricopa and Pima Counties, Arizona, found that

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[44] United States Department of Health and Human Services. "Head Start Program Information Report." Available at: https://eclkc.ohs.acf.hhs.gov/data-ongoing-monitoring/article/program-information-report-pir

[45] Patel KM, Malik AA, Lee A, et al. COVID-19 vaccine uptake among US child care providers. *Pediatrics.* 2021; doi: https://pubmed.ncbi.nlm.nih.gov/34452977/

[46] Lam-Hine T, McCurdy SA, Santora L, et al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School — Marin County, California, May–June 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1214–1219. DOI: http://dx.doi.org/10.15585/mmwr.mm7035e2

[47] Lam-Hine T, McCurdy SA, Santora L, et al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School — Marin County, California, May–June 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1214–1219. DOI: http://dx.doi.org/10.15585/mmwr.mm7035e2

schools without mask requirements were 3.5 times more likely to have COVID-19 outbreaks compared with schools that started the year with mask requirements.[48] This finding is consistent with another study that included 520 counties across the United States during the period July 1 to September 4, 2021, reporting that counties without school mask requirements experienced larger increases in pediatric COVID-19 case rates after the start of school compared to counties that had school mask requirements.[49]

Prior to the availability of COVID-19 vaccines in the United States, during the period from September to October 2020, ACF collaborated with CDC to conduct a mixed-methods study in Head Start programs in eight states (Alaska, Georgia, Idaho, Maine, Missouri, Texas, Washington, and Wisconsin). The study found that implementing and monitoring adherence to recommended mitigation strategies, such as mask use, can reduce risk for SARS-COV-2 transmission in Head Start settings. It also showed that Head Start and Early Head Start programs that successfully implemented CDC-recommended guidance for childcare programs were able to continue offering safe in-person learning.[50]

A survey of the U.S. child care workforce conducted between May 26 and June 23, 2021, found that the overall COVID-19 vaccine uptake among child care providers was 78.2 percent, which was higher than the general U.S. adult population (65 percent).[51] The rate among Head Start and Early Head Start staff in center-based settings specifically was 73 percent, though lower in home-based programs. That 73 percent is a nationwide

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[48] Jehn M, McCullough JM, Dale AP, et al. Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks — Maricopa and Pima Counties, Arizona, July–August 2021. MMWR Morb Mortal Wkly Rep 2021;70:1372–1373. DOI: http://dx.doi.org/10.15585/mmwr.mm7039e1

[49] Budzyn SE, Panaggio MJ, Parks SE, et al. Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements — United States, July 1–September 4, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1377–1378. DOI: http://dx.doi.org/10.15585/mmwr.mm7039e3

[50] Coronado F, Blough S, Bergeron D, et al. Implementing Mitigation Strategies in Early Care and Education Settings for Prevention of SARS-CoV-2 Transmission — Eight States, September–October 2020. MMWR Morb Mortal Wkly Rep 2020; 69:1868-1872. DOI: http://dx.doi.org/10.15585/mmwr.mm6949e3

[51] Patel KM, Malik AA, Lee A, et al. COVID-19 vaccine uptake among US child care providers. Pediatrics. 2021; doi: https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e1.htm

figure. It could be much less in certain areas. Also, it is 73 percent of adults, but none of the children in the programs can be vaccinated. While other teachers and staff members might be protected from an unvaccinated staff, the concern remains the protection of children and families. Depending on the role in the program of the 27 percent of Head Start staff that are unvaccinated, it could result in roughly 250,000 children who are in the care of an unvaccinated adult. This IFC is critical in order to increase that percentage, given the importance of protecting young children from exposure to SARS-CoV-2, including more transmissible variants.

Data show COVID-19 vaccination requirements are effective in increasing vaccination rates among employees. Other industries that have implemented vaccine requirements have seen substantial increases in the percent of their workforce receiving the vaccine.[52, 53] Two weeks following the Governor of Washington's vaccine requirement for State workers, according to the Washington State Department of Health**,** the weekly vaccination rate increased 34 percent.[54]

Reduced Program Closures

Requiring staff to get fully vaccinated for COVID-19 is critical to reduce program closures due to SARS-CoV-2 exposures. Such closures may impose multiple hardships on Head Start children and families. The children and families served by Head Start are largely comprised of individuals who experience economic hardship and have been historically underserved and marginalized. In 2019, 80 percent of children served by

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[52] Hirsch, L. (2021, September 30). *After mandate, 91% of Tyson workers are vaccinated*. The New York Times. Retrieved November 3, 2021, from https://www.nytimes.com/2021/09/30/business/tyson-foods-vaccination-mandate-rate.html; Josephs, L. (2021, September 29). Nearly 600 United Airlines employees face termination for failing to comply with Vaccine Mandate. CNBC. Retrieved November 3, 2021, from https://www.cnbc.com/2021/09/28/unvaccinated-united-airlines-staff-faces-termination-as-early-as-today.html

[53] White House. "WHITE HOUSE REPORT: Vaccination Requirements Are Helping Vaccinate More People, Protect Americans from COVID-19, and Strengthen the Economy." Available at: https://www.whitehouse.gov/wp-content/uploads/2021/10/Vaccination-Requirements-Report.pdf

[54] White House. "Path Out of the Pandemic." Available at: https://www.whitehouse.gov/covidplan/#schools; Mikkelsen, D. (2021, August 27). *Covid-19 vaccinations increase in Washington following mandates, Spike in cases*. king5.com. Retrieved November 3, 2021, from https://www.king5.com/article/news/local/covid-19-vaccinations-increase-in-washington/281-1af4cc43-2d7f-4e77-a2fd-0fad28d0c4f3

Head Start were Black, Indigenous, or persons of color.[55] Thirty-eight percent of children were dual language learners, with a language other than English spoken in the home (sometimes in addition to English). The mean annual household income for families was $26,000. Fifty-nine percent of children had a mother with a high school diploma or less, and the majority (77 percent) had a mother who was either working full-time, working part-time, or looking for work. Fifty-seven percent and 52 percent of children's families received SNAP benefits and WIC benefits, respectively. Thirty-one percent of children lived in a household where parents reported household food would often or sometimes run out and they did not have money to purchase more. Twenty-four percent of children's mothers had moderate or severe depressive symptoms, as measured by a clinical depression screening tool.

Head Start programs provide critical services to meet the health, nutrition, and early learning needs of these children and families. Programs provide healthy nutritious meals to children and provide diapers for babies and toddlers, every day they are at the program. Programs ensure children are brushing their teeth and provide critical mental health services. Programs also provide high-quality early education services to promote the overall learning and development of children and prepare them for entry into kindergarten. If a program must close its facilities for a designated period of time due to an outbreak of SARS-CoV-2 infections, children at-risk will not receive these critical in-person services. Further, program closures limit the ability of Head Start families to work or seek educational opportunities. As summarized previously, Head Start families earning low wages and very likely do not have sick leave to care for children while they are in quarantine. Staying home for intermittent closures, rather than working, imposes

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[55] All descriptive statistics in this paragraph are from: Kopack Klein, A., Aikens, N., Li, A., Bernstein, S. Reid, N., Dang, M., Blesson, E…. Tarullo, L. (2021). Descriptive Data on Head Start Children and Families from FACES 2019: Fall 2019 Data Tables and Study Design, OPRE Report 2021-77, Washington, DC: U.S. Department of Health and Human Services.

significant financial costs on Head Start families. It also places the families at risk of losing their employment if they must take unpaid leave to care for children in quarantine. Families rely on Head Start programs to provide stable and reliable early care and education services to their children, and the effects of intermittent closures are significant.

As alluded to previously, program closures also create instability and stress for children and families. They disrupt children's opportunities for learning, socialization, nutrition, and continuity and routine. In June 2020, the Defending the Early Years organization released a survey to better understand the impact COVID-19 has had on young children, their families, and their teachers. Balancing working from home and supporting children was the number one challenge for parents. This challenge was especially acute for families with multiple children in different grade levels or with one child under the age of four years. Fifty-five percent of parents of young children reported they were somewhat-to-very concerned about financial issues (e.g., job loss) due to the COVID-19 pandemic.[56] Other issues of concern related to early childhood education program and school closures and/or virtual or remote learning have compounded to create uniquely difficult challenges for families. These compounding issues include missed opportunities for academic instruction, children falling behind, children missing out on social interaction and play with peers, challenges to safe reopening, and increase in children's stress.

Survey data from February 2021 indicates that a diminished ability to attend early childhood programs like Head Start in-person, is related to an increase in social and emotional difficulties for children, a decrease in support for children with disabilities, and

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[56] Jones, Denisha. Education Resources Information Center. "The Impact of COVID-19 on Young Children, Families, and Teachers." *Defending the Early Years* (2020). Available at: https://eric.ed.gov/?id=ED609168

an increase in parental stress due to lack of affordable child care including loss of jobs and wages.[57] The RAPID-EC Survey describes this as a "chain of hardship" where families loss of jobs results in difficulty paying for basic needs such as food and housing further negatively impacting family well-being including a rise in emotional distress for parents and children.[58] These disruptions can be particularly difficult for children and families experiencing homelessness, a population Head Start programs are required to prioritize (45 CFR §1302.15(c)). Of all families enrolled in Head Start programs, about 6.2 percent or 42,334 families experienced homelessness during the 2020-2021 program year.[59] Given the greater risks to the health and development of young children experiencing homelessness, stable Head Start services are critically important for these families.[60]

School closures, heightened stress, loss of income, and social isolation resulting from the COVID-19 pandemic are all stressors that have increased the risk for child abuse and neglect.[61] Head Start programs are required to prioritize foster children for enrollment, and there was an increase in the rate of children in foster care served in Head Start from 3.5 percent in 2019 to 3.8 percent in 2021. Program closures and remote learning during the pandemic contribute to disruption of service access for these children,

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[57] Barnett, W.S & Jung, K. Seven Impacts of the Pandemic on Young Children and their Parents: Initial Findings from NIEER's December 2020 Preschool Learning Activities Survey. February 2021. Available at: NIEER_Seven_Impacts_of_the_Pandemic_on_Young_Children_and_their_Parents.pdf

[58] Fisher,P, Lombardi, J. & Kendall Taylor, N. A day in the life of a pandemic/ https://medium.com/rapid-ec-project/a-year-in-the-life-of-a-pandemic-4c8324dda56b

[59] United States Department of Health and Human Services. "Head Start Program Information Report." Available at: https://eclkc.ohs.acf.hhs.gov/data-ongoing-monitoring/article/program-information-report-pir

[60] Kiersten: Coughlin, C. G., Sandel, M., & Stewart, A. M. (2020). Homelessness, Children, and COVID-19: A Looming Crisis. *Pediatrics*, 146(2). Available at: https://doi.org/10.1542/peds.2020-1408; Haskett, M. E., Armstrong, J. M., & Tisdale, J. (2016). Developmental Status and Social–Emotional Functioning of Young Children Experiencing Homelessness. Early Childhood Education Journal, 44(2), 119–125.
Available at: https://doi.org/10.1007/s10643-015-0691-8; Weinreb; L., Goldberg, R., Bassuk, E., & Perloff, J. (1998). Determinants of Health and Service Use Patterns in Homeless and Low-income Housed Children. Pediatrics, 102(3), 554–562. Available at: https://doi.org/10.1542/peds.102.3.554

[61] Rodriguez, C.M, Lee, S.J., Ward, K.P., & Pu, D.F. (2021). The Perfect Storm: Hidden risk of child maltreatment during the Covid-19 pandemic. Child Maltreatment, 26(2), 139-151.

who often experience trauma and are most in need of the consistent care, education and comprehensive services that Head Start provides.[62]

Supporting safe and sustained in-person services allows programs to return to fulfilling the critical functions they serve for children and families. All Head Start staff are mandated reporters and programs must have internal procedures in place for staff to report suspected cases of child abuse and neglect. Procedures also include notification to the program's Regional Office immediately if a staff member or volunteer suspects an incident. Agencies must provide training in methods for identifying and reporting suspected child abuse and neglect (45 CFR 1304.52(l)(3)(i)).[63] Research also indicates that Early Head Start can serve as a child abuse and neglect prevention program.[64] The work Head Start programs do to strengthen family economic stability and decrease parental stressors is known to help prevent child abuse. Many programs also provide supports to families experiencing domestic violence (2.5 percent or 24,000 families in 2019 OHS data[65]). This IFC is an important step in decreasing serious risks to very young children and their families.

OHS has been tracking data on the operating status of programs since the onset of the pandemic. In March and April of 2020, more than 90 percent of programs closed all in-person operations for varying lengths of time. By August of 2020, 21 percent of programs had reopened for in-person services, 26 percent remained closed for in-person services due to COVID-19, and the remainder of programs were closed for summer

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[62] Kiersten: Klain, E. J., & White, A. R. (2013). Implementing trauma-informed practices in child welfare. CITY: State Policy Advocacy Reform Center. Retrieved from http://www.centerforchildwelfare.org/kb/TraumaInformedCare/ImplementingTraumaInformedPracticesNov13.pdf

63 Office of Head Start Information Memorandum. Mandated Reporting of Child Abuse and Neglect ACF-IM-HS-15-04. September 18, 2015. Available at: https://eclkc.ohs.acf.hhs.gov/policy/im/acf-im-hs-15 04#:~:text=Staff%20who%20need%20help%20identifying,800%2D422%2D4453).&text=All%20Head%20Start%20programs%20must,of%20child%20abuse%20and%20neglect

[64] Child Trends. "How Early Head Start Prevents Child Maltreatment." November 1, 2018. Available at: https://www.childtrends.org/publications/how-early-head-start-prevents-child-maltreatment.

65 United States Department of Health and Human Services. "Head Start Program Information Report." Available at: https://eclkc.ohs.acf.hhs.gov/data-ongoing-monitoring/article/program-information-report-pir

months as regularly scheduled. In December 2020, data show the highest combined percentage (67 percent) of Head Start centers operating as solely virtual/remote or as hybrid, with an additional five percent, or 878, of centers closed. Together, these virtual/remote, hybrid, and closed centers account for over 13,500 centers nationwide. Each center represents many families for whom unpredictable closures and transitions to virtual learning come at a cost, may present difficult decisions between employment and child care responsibilities, and could result in major financial impacts on their household.

July 2021 data show that two percent of centers (393) were closed due to COVID-19, 14 percent of centers were operating in a virtual/remote service delivery model (2,861), and 45 percent of centers were operating in a hybrid service delivery model (9,181). Only 35 percent of centers (7,240) were operating fully in person.

September 2021 center operating status data shows 73 percent (14,917) of the centers are open for in-person only services, 14 percent (2,892) are operating in a hybrid model of in-person and virtual/remote services, and 4 percent (835) are open for virtual/remote only. Two percent (324) of centers remain entirely closed due to COVID-19 and the remaining 7 percent of centers are unreported, closed for the season, or closed due to a natural disaster. The increase in the number of programs delivering services in-person only is consistent with the expectations OHS outlined in May 2021 that programs move toward fully in-person services as soon as possible by January 2022, factoring in local health conditions.[66] This data also show that while closures declined, at least 20 percent of programs are closed, operating a virtual/remote service delivery model only, or in a hybrid model. Programs need to be able to resume fully in-person services to meet the needs of children and families, for all the reasons discussed in this section of the IFC.

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[66] Office of Head Start. Office of Head Start (OHS) Expectations for Head Start Programs in Program Year (PY) 2021–2022. May 20, 2021. Available at: https://eclkc.ohs.acf.hhs.gov/policy/pi/acf-pi-hs-21-04

A vaccination requirement and consistent and correct mask use are critical in mitigating SARS-CoV-2 transmission and keeping Head Start programs open. Program closures impede Head Start families from participating in the workforce, impose financial hardship on low wage workers who may not have paid time off to care for children who are in quarantine, create instability for children and families who depend on the Head Start program, and delay a full economic recovery for the nation.

HHS Secretary's Extension of Public Health Emergency

On January 31, 2020, Health and Human Services Secretary Alex M. Azar II determined that a public health emergency (PHE) exists retroactive to January 27, 2020,[67] under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. This declaration has been extended every 90 days since then and most recently on October 18, 2021. The current PHE declaration extends until mid-January 2022.

C. Waiver of Proposed Rulemaking

In accordance with the Administrative Procedure Act (APA), 5 U.S.C. 553, ACF ordinarily publishes a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule before the provisions of the rule take effect. . Specifically, 5 U.S.C. 553(b) generally requires the agency to publish a notice of the proposed rule in the Federal Register that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Section 553(c) further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Section 553(b)(B) authorizes the agency to waive these procedures, however, if the agency finds good cause

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[67] United States Department of Health and Human Services. "Public Health Emergency." January 31, 2020. Available at: https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVDI-15Oct21.aspx

that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The 2021 outbreaks associated with the SARS-Cov-2 Delta variant have shown that current levels of COVID-19 vaccination coverage up until now have been inadequate to protect Head Start staff, children, and families. The data showing the effectiveness of vaccination indicate to us that we cannot delay taking this action in order to protect the health and safety of children and families~~,~~ and the staff providing care.

We recognize that newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level; nonetheless, they remain substantially elevated relative to numbers seen in May and June 2021, just before the Delta variant became the predominant strain circulating in the U.S.[68] And while cases are trending downward in some states, there are emerging indications of potential increases in others—particularly northern states where the weather has begun to turn colder.[69] The United States experienced a large COVID-19 wave in the winter of 2020. As of November 18, 2021, over 30 percent of people aged 12 years and older in the United States remain not fully vaccinated—and this situation could pose a threat to the country's progress on the COVID-19 pandemic, potentially incurring a fifth wave of COVID-19 cases.[70]

The efficacy of COVID-19 vaccinations has been demonstrated.[71] An ASPE report published on October 5, 2021, found that COVID-19 vaccines are a key component in controlling the COVID-19 pandemic. Clinical data show vaccines are

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[68] https://covid.cdc.gov/covid-data-tracker/#datatracker-home.
[69] https://www.cdc.gov/flu/professionals/acip/background-epidemiology.htm.
[70] Centers for Disease Control. "COVID Data Tracker." November 18, 2021. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total
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[71] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.

highly effective in preventing COVID-19 cases and severe outcomes including hospitalization and death. Vaccines continue to be effective in preventing COVID-19 associated with the now-dominant Delta variant.[72, 73]

In addition to preventing morbidity and mortality associated with COVID-19, the vaccines also appear to be effective against asymptomatic SARS-CoV-2 infection. A recent study of health care workers in 8 states found that, from December 14, 2020, through August 14, 2021, full vaccination with COVID-19 vaccines was 80 percent effective in preventing RT-PCR–confirmed SARS-CoV-2 infection among frontline workers.74 Emerging evidence also suggests that vaccinated people who become infected with Delta have the potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk.75 For example, in a study of breakthrough infections among health care workers in the Netherlands, SARS-CoV-2 infectious virus shedding was lower among vaccinated individuals with breakthrough infections than among unvaccinated individuals with primary infections.76

As noted earlier in this section, a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to children from unvaccinated staff, continuing strain on the health care system, and known efficacy and safety of available vaccines, have persuaded us that a vaccine requirement for Head Start staff, certain contractors, and volunteers is an essential component of the nation's COVID-19 response. Further, it would endanger the health and safety of staff, children and families, and be contrary to the public interest to delay imposing the vaccine mandate. Therefore, we believe it would be impracticable and contrary to the public interest for us to undertake normal

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[72] https://www.nejm.org/doi/full/10.1056/nejmoa2108891.
[73] https://www.mayoclinic.org/coronavirus-covid-19/covid-variant-vaccine.
[74] https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w.
[75] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#ref43.
[76] https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full.pdf.

notice and comment procedures and to thereby delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. §§ 552(d), 553(b)(B). For those same reasons, as authorized by subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act or CRA), 5 U.S.C. 808(2), we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under the CRA. Therefore, we find there is good cause to waive the CRA's delay in effective date pursuant to 5 U.S.C. 808(2).

IV. Background

Since its inception in 1965, Head Start has been a leader in supporting children from low-income families in reaching kindergarten healthy and ready to thrive in school and life. The program was founded on research showing that health and wellbeing are pre-requisites to maximum learning and improved short- and long-term outcomes. In fact, OHS identifies health as the foundation of school readiness.

The Head Start Program Performance Standards require children to be up to date on immunizations and their state's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) schedule (45 CFR 1302.42(b)(1)(i)). When children are behind on immunizations or other care, Head Start programs are required to ensure they get on a schedule to catch up. Additionally, education, family service, nutrition, and health staff help children learn healthy habits, monitor each child's growth and development, and help parents access needed health care. It is vitally important that enrolled pregnant women and children from birth to five years can access in-person services. When children are able to participate in their regular, in-person program options, they form a secure attachment to and relationship with their Head Start teachers. A large body of research demonstrates that a secure attachment with caregivers is a critical foundation for

children to learn and explore their environment.[77] Furthermore, education staff who see children in person are better able to monitor their progress and individualize teaching and learning. The youngest children, children from birth to five years, need physical interaction with materials and in-person support for optimal learning. Screen based learning is much less effective and necessarily limited in the number of hours. Finally, as many parents return to work, they need the assurance that their children are in a safe and high-quality learning environment.

It is equally important that the Head Start program itself is safe for all children, families, and staff. For this reason, the Head Start Program Performance Standards specify that the program must ensure staff do not pose a significant risk of communicable disease (45 CFR 1302.93(a)). Ensuring that children and families can benefit from program services as safely as possible is OHS' highest priority. While this is always important, the COVID-19 pandemic highlights the need to ensure staff are as protected as possible so that children under age 5 years, who cannot yet be vaccinated, are also protected. Fully vaccinated staff are at much lower risk of infection and therefore, pose lower transmission risk to the young unvaccinated children in their care.[78] Young children who get the virus can also spread it to others in their homes and communities. Ensuring Head Start staff are fully vaccinated significantly reduces the possibility of the program playing an unwitting part in community spread of SARS-CoV-2.

On October 29, 2021 the U.S. Food and Drug Administration authorized the Pfizer-BioNTech mRNA vaccine for COVID-19 for use in children ages five to 11. On November 2, 2021, CDC adopted the CDC Advisory Committee on Immunization

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[77] Bergin, C., & Bergin, D. (2009). Attachment in the classroom. *Educational Psychology Review, 21*(2), 141-170.; Rees, C. (2007). Childhood attachment. *British Journal of General Practice, 57*(544), 920-922.; Sierra, P. G. (2012). Attachment and preschool teacher: An opportunity to develop a secure base. *International Journal of Early Childhood Special Education (INT-JECSE), 4*(1), 1-16.

[78] Centers for Disease Control and Prevention. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." November 10, 2021.
Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html

Practices' (ACIP) recommendation that children 5 to 11 years old be vaccinated for COVID-19 with the Pfizer-BioNTech pediatric vaccine. While Head Start does serve some children who are currently eligible for a vaccine, children five and older only represented 1.11 percent of children enrolled in Head Start programs during the 2020-2021 program year (Office of Head Start - Program Information Report [PIR] Enrollment Statistics Report - 2021 - National Level). As of November 11, 2021, there is no pediatric COVID-19 vaccine available for children younger than age five years in the United States.

To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

V. Provisions of the Interim Final Rule

This interim final rule (IFR) adds new provisions to the Head Start Program Performance Standards to require: (1) effective immediately, and with exceptions discussed below, universal masking for all individuals two years of age and older regardless of program option, (2) all Head Start staff, certain contractors, and volunteers in classrooms or working directly with children to be fully vaccinated for COVID-19, with exemptions discussed below, and (3) for those granted an exemption to the requirement specified in (2) at least weekly testing for current SARS-CoV-2 infection.

The definition of *staff* in §1305.2 is "paid adults who have responsibilities related to children and their families who are enrolled in programs." Consistent with that

definition, "all staff" as noted in this IFC, refers to all staff who work with enrolled Head Start children and families in any capacity regardless of funding source. The term "Head Start" is inclusive of Head Start, Early Head Start, and Early Head Start-Child Care Partnerships.

Consistent with CDC's guidance, in general, fully vaccinated [79] means

(i) a person's status 2 weeks after completing primary vaccination with a COVID-19 vaccine with, if applicable, at least the minimum recommended interval between doses in accordance with the approval, authorization, or listing that is:

(A) Approved or authorized for emergency use by the Food and Drug Administration (FDA);

(B) Listed for emergency use by the World Health Organization (WHO); or

(C) Administered as part of a clinical trial at a U.S. site, if the recipient is documented to have primary vaccination with the "active" (not placebo) COVID-19 vaccine candidate, for which vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board) or if the clinical trial participant at U.S. sites had received a COVID-19 vaccine that is neither approved nor authorized for use by FDA but is listed for emergency use by WHO; or

(ii) A person's status 2 weeks after receiving the second dose of any combination of two doses of a COVID-19 vaccine that is approved or authorized by the FDA, or listed as a two-dose series by WHO (i.e., a heterologous primary series of such vaccines, receiving doses of different COVID-19 vaccines as part of one primary series). The second dose of the series must not be received earlier than 17 days (21 days with a 4-day grace period) after the first dose.

A. Masking Requirement

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[79] Centers for Disease Control and Prevention. "When You've Been Fully Vaccinated." October 15, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html

This IFC adds a new provision to part1302, subpart D – Health Program Services in § 1302.47, Safety practices. Section 1302.47(b)(5), Safety practices, specifies the appropriate practices all staff and consultants follow to keep children safe during all activities. This IFC creates a new paragraph (vi) that requires universal masking for all individuals aged 2 years and older when there are two or more individuals in a vehicle owned, leased, or arranged by the Head Start program; indoors in a setting when Head Start services are provided; and for those not fully vaccinated, outdoors in crowded settings or during activities that involve sustained close contact with other people. The Office of Head Start notes that being outdoors with children inherently includes sustained close contact for the purposes of caring for and supervising children.

There are different types of masks. Head Start staff should choose a mask that is comfortable to wear and fits snugly. It must cover one's mouth, nose, and chin. It can fasten around the ears or the back of the head, as long as it stays in place when one talks and moves. Masks with vents or exhalation valves are not allowed because they allow unfiltered breath to escape the mask. For more information on masks, programs can consult Your Guide to Masks | CDC .

Purchasing masks needed for staff to fulfill their duties and responsibilities and for children is considered an allowable use of Head Start program funds, as well as the COVID-19 response funds and the American Rescue Plan funds.[80] Programs should have masks available to provide to children when they do not have their own mask.

This requirement is effective immediately upon publication of this IFC. Exceptions are noted for when individuals are eating or drinking; for children when they are napping; for the narrow subset of persons who cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act

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[80] Office of Head Start. "FY 2021 American Rescue Plan Funding Increase for Head Start Programs." May 4, 2021. Available at: **https://eclkc.ohs.acf.hhs.gov/policy/pi/acf-pi-hs-21-03**

(ADA), consistent with CDC guidance on disability exemptions[81]; and for children with special health care needs, for whom programs should work together with parents and follow the advice of the child's health care provider for the best type of face covering. It should be noted that like all new skills, children will need to be taught the proper way to put a mask on and keep a mask on. While children are adaptable, they are still in the early stages of development and may need reminders and reinforcements to comply with this new practice. It is imperative that Head Start staff abide by the Standards of Conduct outlined in 1302.90 Personnel Policies in the Head Start Program Performance Standards namely that staff, consultants, contractors, and volunteers implement positive strategies to support children's well-being and do not use harsh disciplinary practices that could endanger the health or safety of children.

B. Vaccination Requirement

This IFC adds four new provisions to part 1302, subpart I – Human Resources Management in § 1302.93, Staff health and wellness, and § 1302.94, Volunteers. Section 1302.93(a), Staff health and wellness, states that "the program must ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program that cannot be eliminated or reduced by reasonable accommodation, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act." This IFC adds a new paragraph (a)(1) to § 1302.93 requiring all staff, and those contractors whose activities involve contact with or providing direct services to children and families, to be fully vaccinated for COVID-19, except for those (i) for whom a vaccine is medically contraindicated, (ii) for whom medical necessity requires a delay in vaccination,[82] or (iii) who are legally entitled to an accommodation

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[81] Centers for Disease Control. Order: Wearing of face masks while on conveyances and at transportation hubs. January 21, 2021. Available at: **Order: Wearing of face masks while on conveyances and at transportation hubs | Quarantine | CDC**

[82] As defined by CDC's informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (CDC, September 29, 2021).

with regard to the COVID-19 vaccination requirement based on an applicable Federal law. It also adds a new paragraph (a)(2) indicating that those who are granted an exemption outlined in (a)(1)(i) through (iii) must undergo testing at least weekly for current SARS COV-2 infection..

The additions made to § 1302.94, Volunteers, mirrors that of § 1302.93, Staff health and wellness. This IFC also adds a new paragraph (a)(1) to § 1302.94, Volunteers, that requires all volunteers who are in classrooms or working directly with children other than their own must be fully vaccinated for COVID-19, except for those (i) for whom a vaccine is medically contraindicated, (ii) for whom medical necessity requires a delay in vaccination,[83] or (iii) who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirement based on an applicable Federal law. It also adds a new paragraph (a)(2) indicating that those who are granted an exemption outlined in paragraphs (a)(1)(i) through (iii) must undergo testing at least weekly for current SARS-CoV-2 infection. The costs associated with regular testing for those granted an exemption are an allowable use of Head Start funds so long as it is included in a program's policies and procedures. While paying for the costs associated with regular testing is allowable use of Head Start funds, it is not a requirement. Programs should consider whether they can sustain continued funding for testing if/when the COVID-19 funds are exhausted. Finally, we have also revised § 1302.94 to remove the word "regular" from paragraph (a). We believe it is important for all volunteers to adhere to these requirements not just those who regularly volunteer in the program.

Programs may use SARS-CoV-2 testing for all staff, regardless of vaccination status, as an additional mitigation strategy with the COVID-19 vaccines, and those granted exemptions are required to undergo testing, but testing alone is not an alternative

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[83] As defined by CDC's informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (CDC, September 29, 2021).

to the COVID-19 vaccination requirement specified in §1302.93 and §1302.94. This is a key difference between this IFC and the COVID-19 Vaccination and Testing; Emergency Temporary Standard, published, by the Occupational Safety and Health Administration (OSHA) on November 5, 2021, which requires employers with 100 or more employees to develop, implement, and enforce a mandatory COVID-19 vaccination policy, unless they adopt a policy requiring employees to choose to either be vaccinated or undergo regular SARS-Cov-2 testing and wear a face covering. Whereas OSHA allows employers to offer an option for testing and face coverings, this IFC does not permit a testing and face coverings option for individuals without an approved vaccine exemption. The rationale for the difference is that ACF is acting under statutory and regulatory standards that are different from OSHA's. In general, the Head Start Act requires standards for a safe environment for staff, children, and other participants.

Documentation of Vaccination Status

The Head Start Act at section 647 (42 USC 9842) has a provision on record-keeping, which allows the Secretary to require certain records be kept and to support OHS in conducting its oversight of programs through monitoring. Pursuant to the statutory recordkeeping requirement in section 647 of the Head Start Act (42 U.S.C. 9842) and in order to ensure programs are complying with the vaccination requirements of this IFC, we are requiring that they track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination, such as recent receipt of monoclonal antibodies or convalescent plasma. Vaccination exemption requests and outcomes must also be documented, discussed further in section II.A.5. of this IFC. This documentation will be an ongoing process as new staff are onboarded.

While program staff may not have personal medical records on file with their employer, all staff COVID-19 vaccines must be appropriately documented by the

provider or supplier. All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files, pursuant to the ADA and the Rehabilitation Act.

Examples of acceptable forms of proof of vaccination include:

- CDC COVID-19 vaccination record card (or a legible photo of the card),
- Documentation of vaccination from a health care provider or electronic health record, or
- State immunization information system record.

If vaccinated outside of the United States, a reasonable equivalent of any of the previous examples would suffice.

Programs have the flexibility to use the appropriate tracking tools of their choice. For those who would like to use it, CDC provides a staff vaccination tracking tool that is available on the NHSN website (https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html). This is a generic Excel-based tool available for free to anyone, not just NHSN participants, that facilities can use to track COVID-19 vaccinations for staff members.

Exemption Process

Under Federal law, including the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964, staff, contractors, and volunteers who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance may in some circumstances be granted an exemption, as discussed in II.B of this IFC. Head Start staff included in this IFC must be able to request an exemption from these COVID-19 vaccination requirements. Additionally, programs following CDC guidelines and the new requirements in this IFC may also be required to provide reasonable accommodations, to the extent required by federal law, for employees who request and receive exemption from vaccination because

of a disability, medical condition, or sincerely held religious belief, practice, or observance.

In support of the new requirements in §§ 1302.93 and 1302.94, it is the responsibility of Head Start programs to establish a process for reviewing and reaching determinations regarding exemption requests (e.g., disability, medical conditions, sincerely held religious beliefs, practices, or observances). Programs must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the program's decision on the request, and any accommodations that are provided. Requests for exemptions based on an applicable federal law must be documented and evaluated in accordance with applicable Federal law and each program's policies and procedures. As is relevant here, this IFC preempts the applicability of any state or local law providing for exemptions to the extent such law provides broader exemptions than provided for by federal law and are inconsistent with this IFC.

For staff members, contractors, and volunteers who request a medical exemption from vaccination, all documentation confirming recognized clinical contraindications to COVID-19 vaccines or medical need for delay, and which supports the request, must be signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws. Such documentation must contain all information specifying which of the authorized or approved COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications or the recognized clinical reasons necessitating delay in vaccination; and a statement by the authenticating practitioner recommending that the staff member be exempted from the program's COVID-19 vaccination requirements based on the recognized clinical contraindications or allowed to delay vaccination.

For more information, Head Start programs can refer to a resource produced by the Equal Employment Opportunity Commission (EEOC), which is responsible for enforcing federal laws that prohibit employment-related discrimination based on a person's race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin, age (40 or older), disability, or genetic information. The EEOC resource, What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, available at What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws | U.S. Equal Employment Opportunity Commission (eeoc.gov), should be helpful in navigating employees' requests for accommodations (EEOC, October 25, 2021).

In granting such exemptions or accommodations, programs must ensure that they minimize the risk of transmission of SARS-CoV-2 to at-risk individuals, in keeping with their obligation to protect the health and safety of staff, children and families. To that end, it is a reasonable alternative that staff, contractors, and volunteers granted an accommodation be required to undergo testing at least weekly for current SARS-CoV-2 infection. Because unvaccinated employees are at higher risk of SARS-CoV-2 infection, and SARS-CoV-2 transmission among individuals without symptoms is a significant driver of COVID-19, ACF has determined it is necessary to prevent the pre-symptomatic and asymptomatic transmission of SARS-CoV-2 from unvaccinated staff, contractors and volunteers, through a requirement for a weekly screening test.[84] Although more regular screening testing (e.g., twice weekly) may identify even more cases, ACF has decided to require a minimum testing of only on a weekly basis, which is in line with CDC recommendations.

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84 OSHA. "COVID-19 Vaccination and Testing; Emergency Temporary Standard." November 5, 2021. Available at: **https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard**

In support of this requirement, programs should develop and implement a written SARS-CoV-2 testing protocol for those staff, contractors, and volunteers granted vaccine exemptions. Programs should consult with their Health Services Advisory Committee (HSAC) and local public health officials, along with recommendations from their agency's legal counsel and Human Resources department in the development of a SARS-CoV-2 testing protocol. Programs are encouraged to review guidance from CDC and FDA about selecting SARS-CoV-2 tests and developing related protocols. The costs of regular testing for those granted an exemption are an allowable use of Head Start funds so long as it is included in a program's policies and procedures. While using Head Start funds is allowable, it is not a requirement. It is at the program's discretion to decide if they will pay for the cost of testing, considering such factors as the number of approved exemptions, whether they can sustain continued funding for testing if/when the COVID-19 funds are exhausted, any incentives associated with allowing the use of funds for testing, and whether employees can cover the expenses of testing.

D. Implementation Dates

Due to the urgent nature of the vaccination requirements established in this IFC, we have not issued a proposed rule, as discussed in section C of this IFC. While some IFCs, or provisions within IFCs, are effective immediately upon publication, such as the mask requirement, we understand that instantaneous compliance, or compliance within days, with the vaccine requirement is not possible. Vaccination requires time, especially vaccines delivered in a series. Programs' updates to their policies and procedures also take time to develop. However, in order to provide protection to staff, children, and families, we believe it is necessary to begin staff vaccinations as quickly as reasonably possible. Therefore, we have set the January 31, 2022 as the compliance date for staff to be vaccinated. Although an individual is not considered fully vaccinated until 14 days (2 weeks) after the final dose, staff, certain contractors and volunteers who have received

the final dose of a primary vaccination series by January 31, 2022 are considered to have met the vaccination requirement, even if they have not yet completed the 14-day waiting period. This timing flexibility applies only to the initial implementation of this IFC and has no bearing on ongoing compliance.

The rationale for a different timeline for compliance with the vaccine requirement in this rule relative to the CMS or the OSHA rule is because this timeline in this rule is coordinated with OHS's expectation, communicated through guidance in May 2021, for programs' return to full in-person services. Beginning January 2022, Head Start programs are expected to resume fully in-person services after a period of increased flexibility with virtual and remote services during the pandemic. At this time, OHS will reinstate pre-pandemic practices for tracking and monitoring enrollment as part of the Full Enrollment Initiative. This means that during the first week of February, OHS will evaluate reported enrollment on the last day of January for purposes of the under-enrollment process. Requiring that staff receive their second dose in a two-dose vaccine series, or a single dose in a one-dose vaccine series, by January 31 is consistent with this return to fully in-person services.

VI. Regulatory Process Matters

Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires federal agencies to determine whether a policy or regulation may negatively affect family well-being. If the agency determines a policy or regulation negatively affects family well-being, then the agency must prepare an impact assessment addressing seven criteria specified in the law. ACF believes it is not necessary to prepare a family policymaking assessment, *see* Pub. L. 105–277, because the action it takes in this interim final rule will not have any impact on the autonomy or integrity of the family as an

institution. However, ACF invites public comment on whether the actions set forth in this interim final rule would have a negative effect on family well-being.

Federalism Assessment Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule would preempt some State laws that prohibit employers from requiring their employees to be vaccinated for COVID–19. Consistent with the Executive Order, we find that State and local laws that forbid employers in the State or locality from imposing vaccine requirements on employees directly conflict with this exercise of our statutory authority to protect the health and safety of Head Start participants and their families and ensure the continuation of services by requiring vaccinations for staff, certain contractors, and volunteers and universal masking. As is relevant here, this IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this IFC. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule. The agency has considered other alternatives (for example, relying entirely on measures such as voluntary vaccination, source control alone, and physical distancing) and has concluded that the mandate established by this rule is the minimum regulatory action necessary to achieve the objectives of the statute. Given the transmission rates of the existing strains of coronavirus and their disproportionate impacts on low-income communities served by Head Start programs, we believe that vaccination of almost all staff, certain contractors, and volunteers is necessary to promote and protect program participants and ensure program continuity. The agency has examined case studies from

other employers and concludes that vaccine mandates are vastly more effective than other measures at achieving ideal vaccination rates and the resulting protections. Given the emergency situation with respect to the Delta variant detailed more fully above, time did not permit usual consultation procedures. We are, however, inviting comments on the substance as well as legal issues presented by this rule.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA) allows Congress to review "major" rules issued by federal agencies before the rules take effect, *see* 5 U.S.C. 801(a). The CRA defines a major rule as one that has resulted, or is likely to result, in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets, see 5 U.S.C. 804(2). The Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this action is a major rule because it will have an annual effect on the economy of $100 million or more.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501 et seq., minimizes government-imposed burden on the public. In keeping with the notion that government information is a valuable asset, it also is intended to improve the practical utility, quality, and clarity of information collected, maintained, and disclosed.

The PRA requires that agencies obtain OMB approval, which includes issuing an OMB number and expiration date, before requesting most types of information from the public. Regulations at 5 CFR part 1320 implemented the provisions of the PRA and

§ 1320.3 of this part defines a "collection of information," "information," and "burden." PRA defines "information" as any statement or estimate of fact or opinion, regardless of form or format, whether numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic, or other media (5 CFR 1320.3(h)). This includes requests for information to be sent to the government, such as forms, written reports and surveys, recordkeeping requirements, and third-party or public disclosures (5 CFR 1320.3(c)). "Burden" means the total time, effort, or financial resources expended by persons to collect, maintain, or disclose information.

This IFC establishes new recordkeeping requirements under the PRA. Head Start grant recipients are required as part of this IFC to maintain records on staff vaccination rates. Additionally, Head Start programs are required to develop their own written SARS-CoV-2 testing protocol for current infection for individuals granted vaccine exemptions. To promote flexibility for local programs, there is no standardized instrument associated with the new recordkeeping requirement. As required under the PRA, ACF will submit a request for approval of these recordkeeping requirements. We will initially request approval through an emergency clearance process, allowing for 6 months of approval under the PRA. We will follow the initial approval with a full request, including two public comment periods, to extend approval of the recordkeeping requirement. A separate notice inviting comments on these new recordkeeping requirements will be published in the Federal Register.

In addition to these new recordkeeping requirements, Head Start grant recipients are expected to update their program policies and procedures to ensure costs associated with regular testing for those granted an exemption are an allowable use of Head Start funds. The recordkeeping activity of maintaining program policies and procedures including the associated burden with updating them on an annual basis is already approved under an existing OMB information collection (Control Number 0970-0148).

The separate Federal Register notice will also invite comments on this existing recordkeeping requirement.

VII. Economic Analysis of Impacts

Introduction

We have examined the impacts of this interim final rule under Executive Order 12866, Executive Order 13563, and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe, and OIRA determined, that this interim final rule is an economically significant regulatory action as defined by Executive Order 12866. Thus, this rule has been reviewed by the Office of Information and Regulatory Affairs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the impacts to small entities attributable to the interim final rule are limited in nature, we certify that the interim final rule will not have a significant economic impact on a substantial number of small entities. These impacts are discussed in detail in the Final Small Entity Analysis.

Summary of Costs and Benefits

This interim final rule establishes vaccine, record keeping, and mask requirements to mitigate the spread of SARS-CoV-2 in Head Start programs. We have evaluated the likely impacts of the interim final rule in comparison to a baseline scenario of no new regulation that incorporates projections of COVID-19 vaccine coverage, cases, deaths, and hospital admissions. We anticipate that the requirement that all Head Start staff get fully vaccinated for COVID-19 will induce a substantial portion of unvaccinated staff to get fully vaccinated. We also estimate that the regulation will induce a similar number,

but smaller share, of unvaccinated Head Start volunteers to get fully vaccinated in response to the interim final rule. Some Head Start volunteers are likely also covered by other regulatory actions, which complicates attributing changes in vaccine coverage to any particular regulatory action. We discuss this in greater detail in the Baseline Section and Benefits Section.

The increase in vaccine coverage attributable to the interim final rule will result in substantial health benefits from reductions in COVID-19 mortality and morbidity. We monetize these impacts using a Value per Statistical Life (VSL) for fatal cases, and estimates of the Value per Statistical Case (VSC) that vary by case severity for non-fatal cases. We also predict that reductions in COVID-19 cases among Head Start staff will result in lower absenteeism, including fewer missed days of work for staff infected with SARS-CoV-2 or recovering from COVID-19 and unvaccinated staff quarantining after a close contact tested positive for SARS-CoV-2. We monetize these impacts using a value of time that accounts for time savings for parents and other caregivers for children enrolled at Head Start centers. We estimate a range of total monetized benefits between $200 million and $296 million under a 7% discount rate, and a range between $196 million and $288 million under a 3% discount rate. These monetized benefits cover a time period between the publication date of the interim final rule and March 1, 2022, when our underlying COVID-19 projections end. For our main analysis, we assume that the requirements will be effective for this time horizon, but also consider a scenario in which the requirements are lifted at an earlier date, such as by the COVID-19 Public Health Emergency expiring. The choice of discount rate impacts the benefit estimates through the VSC, which is based on estimates of the Value per Quality-Adjusted Life Year that vary by discount rate.

In addition to the impacts that we monetize in this analysis, we anticipate that the increase in vaccine coverage attributable to the interim final rule will result in indirect

health benefits from reduced transmission of SARS-COV-2, the virus that causes COVID-19. These impacts include reductions in secondary infections from Head Start staff and volunteers to other staff and volunteers, children, and families. We anticipate that the masking requirement will also reduce transmission SARS-COV-2 from individuals covered by the requirement. This impact includes a reduction in transmission from children to Head Start teachers, staff, and other children. We also discuss a mechanism and valuation approach for monetizing benefits from Head Start centers reopening. We discuss these impacts in greater detail in the Benefits Section, and note that they are embedded in a quantitative approach in the Net Benefits section.

We have identified several costs that are attributable to the interim final rule. We monetize the costs of vaccination, which incorporates a value of time for staff and volunteers, and the cost of doses and administration; the costs of the masking requirement; the costs of testing unvaccinated staff and volunteers; and the costs of recordkeeping associated with the interim final rule. We also consider a scenario where a share of unvaccinated Head Start staff quit rather than get fully vaccinated. Under this scenario, these costs would include training replacement staff, and the costs to parents and other caregivers for children enrolled at Head Start center resulting from staff vacancies. We estimate a range of costs between $16 million and $83 million, which cover a time period between the publication of the interim final rule and March 1, 2022, which is consistent with the time horizon adopted for our benefits estimates. These cost estimates do not vary with the discount rate. We also discuss potential additional costs of masking and testing associated with Head Start centers reopening as a result of the interim final rule.

Table 1 presents a summary of the monetized impacts attributable to the interim final rule. All dollar estimates are presented in millions of 2020 dollars. We request comments on these benefit and cost estimates.

Table 1. Summary of Benefits, Costs and Distributional Effects of Interim final rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$247,964,991	$200,294,622	$295,635,335	2020	7%	3 months	
		$242,185,591	$195,986,161	$288,384,996	2020	3%	3 months	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$49,456,037	$15,612,352	$83,299,721	2020	7%	3 months	
		$49,456,037	$15,612,352	$83,299,721	2020	3%	3 months	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages:							

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Growth:							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. [insert reference number]). We request comments on this analysis.

VIII. Alternatives Considered

In making the decision to require vaccination and mask use, ACF considered whether to require other mitigation strategies or combinations of mitigation strategies. The CDC's recently issued guidance on November 10, 2021 reiterates the importance of using multiple prevention strategies in ECE programs.[85] In addition to vaccinations and masks, other strategies noted in this IFC include staying home if sick; handwashing; improving ventilation; screening and diagnostic testing; cleaning and disinfecting; keeping physical distance; and cohorting.

There are two primary reasons that ACF decided to mandate vaccination and mask use. First, Head Start programs have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting. The requirement for staying home when sick is part of §

[85] Centers for Disease Control and Prevention. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." November 10, 2021.
Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html

1302.47(b)(4)(i)(A); hand hygiene (handwashing) is included at § 1302.47(b)(6)(i); cleaning, sanitizing, and disinfecting is at § 1302.47(b)(2)(i); and physical distancing is part of § 1302.47(b)(4)(i)(A), which OHS sees as a strategy for a program's infection control practices). In addition, § 1302.47(b)(1)(iii) states that facilities need to be "free from pollutants, hazards and toxins that are accessible to children and could endanger children's safety," though it is difficult be overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.

Second, as discussed in this IFC, being fully vaccinated forCOVID-19 and using a mask are two of the most effective mitigation strategies available to reduce transmission of COVID-19.[86] With this in mind, ACF determined a federal requirement is necessary. While some agencies and localities have implemented vaccine and masking requirements, many have not. Additionally, vaccine uptake among Head Start staff has not been as robust as hoped for and has been insufficient to protect the health and safety of children and families receiving Head Start services. Combined, these factors leave certain children and families with fewer mitigation strategies in place to protect them than others. It is ACF's responsibility to make sure the environment is as safe as possible for Head Start programs uniformly across all 1,600 grant recipients.

Additionally, although less effective and efficient than vaccination, the CDC has recognized regularly testing unvaccinated individuals for SARS-CoV-2 as a useful tool for identifying asymptomatic and/or pre-symptomatic infected individuals so that they can be isolated,[87] which informed the decision to include in this IFC a testing policy for those granted an exemption. It is also consistent with the CDC's guidance on November 11, 2021, which added screening testing information to its prevention strategies. This

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[86] Centers for Disease Control and Prevention. "Science Brief: COVID-19 Vaccines and Vaccination." September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.
[87] Centers for Disease Control and Prevention. "Overview of Testing for SARS-CoV-2 (COVID-19). October 22, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

guidance notes that in ECE programs, screening testing can help promptly identify and isolate cases, quarantine those who may have been exposed to SARS-CoV-2 and are not fully vaccinated, and identify clusters to reduce the risk to in-person education. The inclusion of a requirement for masking, vaccination and testing, for those staff, contractors and volunteers granted an exemption, ensures the Head Start Program Performance Standards reflect the current science with respect to reducing the spread of SARS-CoV-2 and reducing COVID-19.

ACF also deliberated on the question of whether to require Head Start programs to cover the cost of testing for those granted an exemption or to shift those costs to staff. Head Start staff are not high wage earners, and we recognize it could create hardship for staff granted an exemption to absorb the cost of weekly testing. That said, if programs have many staff who are approved for exemptions, it could be difficult for the program to bear the cost of weekly testing, particularly when their COVID-19 response funds are exhausted. Given these various factors, ACF determined that it is important to make it allowable to use funds at this time, including both COVID-19 response funds and ongoing program funds, for the purpose of testing but allow programs the discretion to make the decision based on budgetary factors, the number of staff approved for an exemption, incentives or other factors. We invite comment on this decision.

ACF also considered whether to tie the universal masking requirement and the testing requirement to SARS-CoV-2 transmission rates. For example, the requirement could make masking voluntary once community transmission drops below a certain level, consistent with CDC guidance. There are more than 1600 Head Start grant recipients, many of which serve multiple communities, cross state lines or serve an entire state. Transmission rates could be significantly different across service areas. For example, one grant recipient in Michigan covers 21 different counties. It would be burdensome for this program to issue separate guidance across its service area to account for changing

transmission levels across those counties. Another grant recipient, Alabama Department of Resources, has a partnership that covers the entire state of Alabama. Again, it would be burdensome for this grant recipient to change its mask guidance for different centers through the state as transmission rates change. ACF values CDC guidance that localities should monitor community transmission in making decisions and has relied on the importance of local health conditions in issuing guidance to Head Start programs. However, in the case of mask use, ACF is prioritizing a clear and transparent policy that is easy for grantees to follow across their service areas. Additionally, children benefit from routine and predictability. ACF determined that the best course of action was not to provide an end date on the universal masking and testing requirement. ACF invites comment on this decision to leave an undetermined end date or whether we should set a finite end date, such as 6 months from the effective date of the rule.

Appendix to Section VII of SUPPLEMENTARY INFORMATION: Economic Analysis of Impacts

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs

Final Regulatory Impact Analysis

Final Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

Office of Head Start

Administration for Children and Families

Department of Health and Human Services

Prepared by

Office of Science and Data Policy

Office of the Assistant Secretary for Planning and Evaluation

Office of the Secretary

Department of Health and Human Services

I. Introduction and Summary

A. Introduction

We have examined the impacts of this interim final rule under Executive Order 12866, Executive Order 13563, and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe, and OIRA

has determined, that this interim final rule is an economically significant regulatory action as defined by Executive Order 12866. Thus, this rule has been reviewed by the Office of Information and Regulatory Affairs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the impacts to small entities attributable to the interim final rule are limited in nature, we certify that the interim final rule will not have a significant economic impact on a substantial number of small entities. These impacts are discussed in detail in the Final Small Entity Analysis.

B. Summary of Costs and Benefits

This interim final rule establishes vaccine, record keeping, and mask requirements to mitigate the spread of COVID-19 in Head Start programs. We have evaluated the likely impacts of the interim final rule in comparison to a baseline scenario of no new regulation that incorporates projections of COVID-19 vaccine coverage, cases, deaths, and hospital admissions. We anticipate that the requirement that all Head Start staff get fully vaccinated against COVID-19 will induce a substantial portion of unvaccinated staff to get fully vaccinated. We also estimate that the regulation will induce a similar number, but smaller share, of unvaccinated Head Start volunteers to get fully vaccinated in response to the interim final rule. Some Head Start volunteers are likely also covered by other regulatory actions, which complicates attributing changes in vaccine coverage to any particular regulatory action. We discuss this in greater detail in the Baseline Section and Benefits Section.

The increase in vaccine coverage attributable to the interim final rule will result in substantial health benefits from reductions in COVID-19 mortality and morbidity. We monetize these impacts using a Value per Statistical Life (VSL) for fatal cases, and estimates of the Value per Statistical Case (VSC) that vary by case severity for non-fatal cases. We also predict that reductions in COVID-19 cases among Head Start staff will result in lower absenteeism, including fewer missed days of work for staff infected or recovering from COVID-19 and unvaccinated staff quarantining after a close contact tested positive for COVID-19. We monetize these impacts using a value of time that accounts for time savings for parents and other caregivers for children enrolled at Head Start centers. We estimate a range of total monetized benefits between $200 million and $296 million under a 7% discount rate, and a range between $196 million and $288 million under a 3% discount rate. These monetized benefits cover a time period between the publication date of the interim final rule and March 1, 2022, when our underlying COVID-19 projections end. For our main analysis, we assume that the requirements will be effective for this time horizon, but also consider a scenario in which the requirements are lifted at an earlier date, such as by the COVID-19 Public Health Emergency expiring. The choice of discount rate impacts the benefit estimates through the VSC, which is based on estimates of the Value per Quality-Adjusted Life Year that vary by discount rate.

In addition to the impacts that we monetize in this analysis, we anticipate that the increase in vaccine coverage attributable to the interim final rule will result in indirect health benefits from reduced transmission of SARS-COV-2, the virus that causes COVID-19. These impacts include reductions in secondary infections from Head Start staff and volunteers to other staff and volunteers, children, and families. We anticipate that the masking requirement will also reduce transmission SARS-COV-2 from

individuals covered by the requirement. This impact includes a reduction in transmission from children to Head Start teachers, staff, and other children. We also discuss a mechanism and valuation approach for monetizing benefits from Head Start centers reopening. We discuss these impacts in greater detail in the Benefits Section, and note that they are embedded in a quantitative approach in the Net Benefits section.

We have identified several costs that are attributable to the interim final rule. We monetize the costs of vaccination, which incorporates a value of time for staff and volunteers, and the cost of doses and administration; the costs of the masking requirement; the costs of testing unvaccinated staff and volunteers; and the costs of recordkeeping associated with the interim final rule. We also consider a scenario where a share of unvaccinated Head Start staff quit rather than get fully vaccinated. Under this scenario, these costs would include training replacement staff, and the costs to parents and other caregivers for children enrolled at Head Start center resulting from staff vacancies. We estimate a range of costs between $16 million and $83 million, which cover a time period between the publication of the interim final rule and March 1, 2022, which is consistent with the time horizon adopted for our benefits estimates. These cost estimates do not vary with the discount rate. We also discuss potential additional costs of masking and testing associated with Head Start centers reopening as a result of the interim final rule.

Table 1 presents a summary of the monetized impacts attributable to the interim final rule. All dollar estimates are presented in millions of 2020 dollars. We request comments on these benefit and cost estimates.

Table 1. Summary of Benefits, Costs and Distributional Effects of Interim final rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$247,964,991	$200,294,622	$295,635,335	2020	7%	3 months	
		$242,185,591	$195,986,161	$288,384,996	2020	3%	3 months	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized $millions/year	$49,456,037	$15,612,352	$83,299,721	2020	7%	3 months	
		$49,456,037	$15,612,352	$83,299,721	2020	3%	3 months	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

II. Economic Analysis of Impacts

A. Background

Since its inception in 1965, Head Start has been a leader in helping children from low-income families reach kindergarten healthy and ready to thrive in school and life. The program was founded on research showing that health and wellbeing are pre-requisites to maximum learning and improved short- and long-term outcomes. In fact, the Office of Head Start identifies health as the foundation of school readiness.

The Head Start Program Performance Standards require children to be up to date on immunizations and their state's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) schedule. When children are behind on immunizations or other care, Head Start programs are required to ensure they get on a schedule to catch up. Additionally, education, family service, nutrition, and health staff help children learn healthy habits, monitor each child's growth and development, and help parents access needed health

care. It is vitally important that enrolled pregnant women and children from birth to 5 can access in person services, especially after so many children spent a year or more away from in-person Head Start services.

It is equally important that the Head Start program itself is safe for all children, families, and staff. For this reason, the Head Start Program Performance Standards specify that the program must ensure staff do not pose a significant risk of communicable disease that cannot be eliminated or reduced by reasonable accommodation, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act. Ensuring that children and families can benefit from program services as safely as possible is the Office of Head Start's highest priority.

COVID-19 has resulted in substantial reductions in in-person Head Start services available to children and their families. As described in greater detail in the Baseline Section, a majority of Head Start centers have moved from fully in-person services to a virtual/remote or a hybrid operating status, while other centers remain closed as a result of a COVID-19 case or outbreak in a program. Without the vaccination and masking requirements of this regulatory action, there is a higher likelihood of transmission of SARS-COV-2 at in-person Head Start settings, which would result in more people at greater risk for COVID-19-related morbidity and mortality, including children returning home and exposing family members. This interim final rule is needed to address the health risks from COVID-19 and to increase the likelihood that Head Start centers are able to reopen or return to in-person services safely.

C. Purpose of the Rule

This regulatory action requires COVID-19 vaccination among all staff employed in Head Start programs, as well as for volunteers that interact with children. The interim final rule also requires mask wearing for all adults and children aged 2 years and older in certain in-person Head Start settings. This regulation also requires recordkeeping of vaccination status for both volunteers and staff. This regulation is necessary to ensure healthy, safe conditions for in-person early care and education services to children and their families enrolled in Head Start programs nationwide. Being fully vaccinated against COVID-19, combined with wearing a mask, are the safest and most effective ways for Head Start programs to mitigate the spread of COVID-19 among the children and families they serve, as well as among staff and volunteers. This action will help more early childhood centers safely remain open and provide needed services to Head Start children and families.

D. Baseline Conditions

This section describes the baseline scenario of no new regulatory action from which the incremental changes to these outcomes from the policy options considered are measured. The scope of this economic analysis is limited to the impacts that are attributable to this regulatory action, which covers more than 20,000 Head Start Centers. The requirements of this interim final rule will cover about 273,000 staff, and a share of the 1 million Head Start volunteers who interact with children in certain in-person Head Start settings. It will also impact a share of the 864,000 children in certain in-person Head Start settings.

On September 9, 2021, President Biden announced the "Path Out of the Pandemic" COVID-19 Action Plan[88], which announced the development of a Head Start vaccination

[88] https://www.whitehouse.gov/covidplan/

requirement, and other elements of a national strategy to combat COVID-19. In our primary analysis, we exclude impacts attributable to other elements of this comprehensive national strategy. For example, the COVID-19 Action Plan announced the development of the Emergency Temporary Standard (ETS) recently issued by the Department of Labor's Occupational Safety and Health Administration (OSHA). Among other provisions, the OSHA ETS requires employers with 100 or more employees to develop, implement, and enforce a mandatory COVID-19 vaccination policy, unless they adopt a policy requiring employees to choose to either be vaccinated or undergo regular COVID-19 testing and wear a face covering. Centers for Medicare & Medicaid Services (CMS) also recently issued an interim final rule with comment period that requires COVID-19 vaccinations for workers in most health care settings that receive Medicare or Medicaid reimbursement.[89] The OSHA action covers over 80 million workers, while the CMS action will apply to approximately 76,000 providers and cover more than 17 million health care workers across the country. Additionally, through Executive Orders 14042, "Ensuring Adequate COVID Safety Protocols for Federal Contractors"[90] and 14043, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees,"[91] and other actions, all federal executive branch employees, including the military, and all federal contractors will be required to be fully vaccinated. In total, the vaccination requirements associated with the Action Plan apply to about 100 million Americans.

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[89] https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination.

[90] https://www.federalregister.gov/documents/2021/09/14/2021-19924/ensuring-adequate-covid-safety-protocols-for-federal-contractors.

[91] https://www.federalregister.gov/documents/2021/09/14/2021-19927/requiring-coronavirus-disease-2019-vaccination-for-federal-employees.

These actions (if implemented, despite ongoing litigation) would likely have significant impacts on the measured outcomes described in this baseline scenario. For example, a recent White House report[92] discusses existing vaccination requirements and summarizes several potential impacts of widespread adoption of such requirements, such as those envisioned in the Action Plan:

> "[V]accination requirements have repeatedly been shown to increase vaccination rates among workers by 20 to 25 percentage points, and in some cases by significantly more. More than three out of four (75.5%) working-aged adult Americans are currently in the labor force, so increasing the share of workers who are fully vaccinated by 20 to 25 percentage points could vaccinate an additional 30 to 38 million working-age Americans, cutting the total share of unvaccinated Americans roughly in half. This could have a major effect on case rates, hospitalization rates, and death rates—preventing future waves of the virus from having as significant an effect as occurred during the spread of the Delta variant. At an individual level, unvaccinated people are more than five times as likely to get a symptomatic case of COVID-19 and more than 10 times as likely to be hospitalized or to die from COVID-19."

There are challenges in extrapolating from private-sector or smaller jurisdiction mandates to broader action by the federal government, especially in regards to the effectiveness of the mandates; however, the estimates contained in the White House Report are broadly consistent with DOL's estimate "that approximately 75.3 million (89.4 percent) of

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[92] https://www.whitehouse.gov/wp-content/uploads/2021/10/Vaccination-Requirements-Report.pdf.

covered employees will be vaccinated when the ETS is in full effect."[93] We exclude these potential spill-over impacts in characterizing our baseline, adopting a regulatory scenario that does not account for other elements of the COVID-19 Action Plan.

The scope of the COVID-19 vaccine requirement is limited to staff at Head Start programs and volunteers that interact with children at Head Start programs. To characterize the baseline scenario, we present forecasts that are specific to the 273,000 staff employed or contracted by Head Start programs,[94] and discuss volunteers separately. We provide quantitative projections of COVID-19 vaccine coverage, and for each of the COVID-19 outcomes described above. Our forecasts are based on COVID-19 Projections maintained by the Institute for Health Metrics and Evaluation (IHME).[95] IHME summarizes its projections in a Data Release Information Sheet:

> "IHME has developed projections for total and daily deaths, daily infections and testing, hospital resource use, and social distancing due to COVID-19 for a number of countries. Forecasts at the subnational level are included for select countries. The projections for total deaths, daily deaths, and daily infections and testing each include a reference scenario: Current projection, which assumes social distancing mandates are re-imposed for 6 weeks whenever daily deaths reach 8 per million (0.8 per 100k). They also include two additional scenarios:

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[93] https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23643.pdf.

[94] https://eclkc.ohs.acf.hhs.gov/about-us/article/head-start-program-facts-fiscal-year-2019.

[95] Institute for Health Metrics and Evaluation (IHME). COVID-19 Mortality, Infection, Testing, Hospital Resource Use, and Social Distancing Projections. Seattle, United States of America: Institute for Health Metrics and Evaluation (IHME), University of Washington, 2020. http://www.healthdata.org/covid/data-downloads. Accessed on November 10, 2022.

> Mandates easing, which reflects continued easing of social distancing mandates, and mandates are not re-imposed; and Universal Masks, which reflects 95% mask usage in public in every location. Hospital resource use forecasts are based on the Current projection scenario. Social distancing forecasts are based on the Mandates easing scenario. These projections are produced with a model that incorporates data on observed COVID-19 deaths, hospitalizations, and cases, information about social distancing and other protective measures, mobility, and other factors. They include uncertainty intervals and are being updated daily with new data. These forecasts were developed in order to provide hospitals, policy makers, and the public with crucial information about how expected need aligns with existing resources, so that cities and countries can best prepare."

We adopt the IHME reference scenario as the source of our baseline forecasts. Since the IHME estimates are "produced with a model that incorporates data on observed COVID-19 deaths, hospitalizations, and cases, information about social distancing and other protective measures, mobility, and other factors," this significantly narrows the wide range of analytic choices that would otherwise be necessary to characterize the baseline scenario. Since the IHME projections cover the entire United States population, we adjust these projections to align with data specific to Head Start. We discuss the specific adjustments in the following narrative.

Vaccine Coverage

A recent study measured "COVID-19 Vaccine Uptake Among U.S. Child Care Providers," with 21,663 respondents, including 1,456 individuals providing services through Head Start or Early Head Start. Among Head Start survey respondents, 73.0%

reported receiving a COVID-19 vaccine. We interpret this to mean that respondents had received at least one dose. This interpretation is consistent with the study's comparison to the general adult population. The authors note that "[t]he survey was active between May 26, 2021 and June 23, 2021," and compare the overall findings to vaccine uptake for the U.S. general adult population of 65%.[96] Since Head Start staff are more likely to be vaccinated than the general adult population, our baseline forecast will reflect this difference. Specifically, we extend this point-in-time estimate to the vaccine coverage forecasts by adopting an assumption that Head Start staff are about 12% more likely to be vaccinated than the general adult population[97], and that this relationship will persist under the time horizon of the baseline scenario of this analysis. As a sample calculation, if the general adult population vaccine coverage rate increases to 67.1%, we would infer a corresponding increase in the Head Start vaccine coverage rate to 74.6%.[98]

The Center for Disease Control and Prevention (CDC) maintains a COVID Data Tracker on its website, which includes a summary of COVID-19 vaccinations in the United States. On November 10, 2021, CDC reports that 58.5% of the total U.S. population are fully vaccinated, and reports 70.3% for a subset of the population that are 18 years of age or older (hereafter, "adults").[99] The IHME COVID-19 projections are reported at a

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[96] Patel KM, Malik AA, Lee A, et al. (2021). "COVID-19 vaccine uptake among US child care providers." *Pediatrics*; doi: 10.1542/peds.2021-053813.

[97] 0.73/0.65 ≈ 1.12. We perform calculations in the model based on the share of individuals who are unvaccinated. The comparable calculation is 1-[(1-0.73)/(1-0.65)] ≈ 0.23, which indicates that Head Start staff are about 23% less likely to be unvaccinated than the general adult population.

[98] 1-[(1-0.671)*(1-0.23)] ≈ 0.75.

[99] https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

population level, and do not contain separate projections that are limited to the adult population. Therefore, generating a baseline forecast of vaccine coverage among Head Start staff from the IHME projections first requires an intermediate step of estimating vaccine coverage for the adult population. We follow the same approach for this adjustment as we discussed to translate adult vaccine coverage estimates to Head Start staff vaccine coverage estimates. Specifically, we calculate a point-in-time relationship using November 10, 2021 CDC data, and assume that this relationship will persist over the time horizon of the analysis. We assume that adults are about 20.1% more likely to be vaccinated than the total population.[100] Combining the adjustments, a population vaccine coverage rate on November 10, 2021 for the total U.S. population of 58.5% would correspond to a 77.1% Head Start vaccine coverage rate.[101]

We assume that vaccination coverage will continue to increase over time and incorporate this into our baseline. For example, the IHME projections indicate U.S. vaccine coverage of 60.0% on November 18, 2021. This estimate increases to 63.4% on March 1, 2022, the last date covered in the most recent IHME projections available at the time of the analysis. We assume that vaccine coverage for Head Start will follow a similar trajectory, after accounting for the adjustments described above, and incorporate this into our baseline. Figure 1 presents forecasts of vaccine uptake under the baseline scenario. These forecasts include the unadjusted IHME projections for the total population, our adjustments to project adult vaccination coverage, and adult vaccination coverage specific to Head Start staff. For Head Start, we anticipate the vaccine coverage rate will

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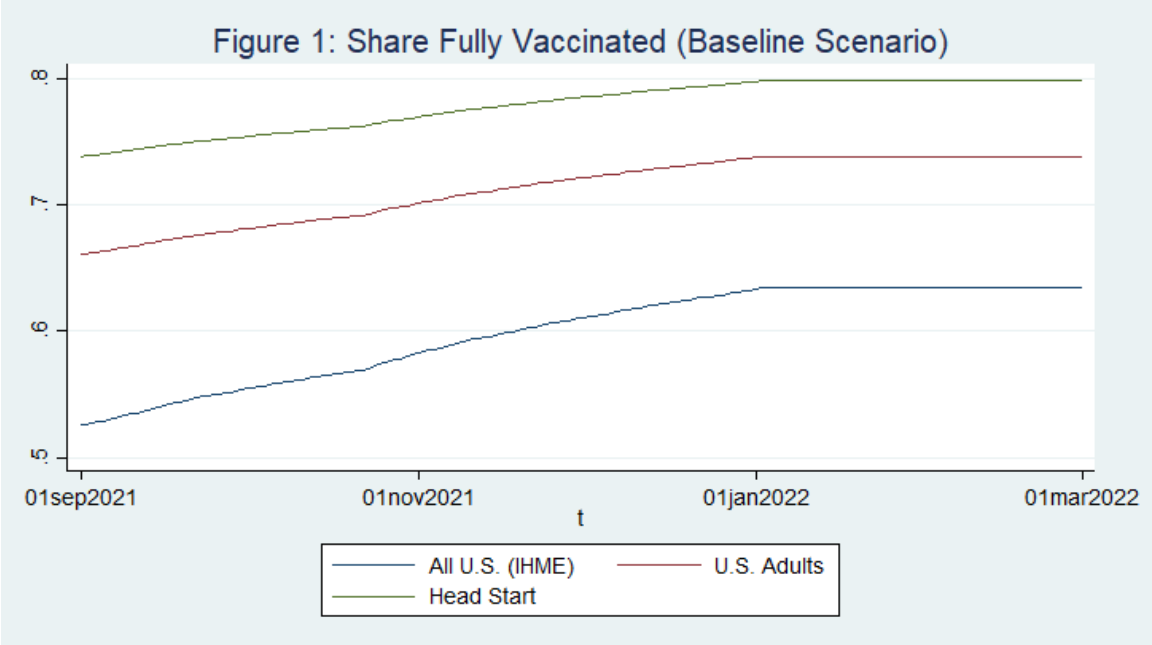
[100] 0.703/0.585 ≈ 1.20. Calculated in the model as 1-[(1-0.703)/(1-0.585)] ≈ 0.284, with the interpretation is adults are about 28.4% less likely to be unvaccinated than the total population .

[101] 1-[(1-.585)*(1-0.284)*(1-0.23)] ≈ 0.771.

increase from 77.9% on November 18, 2021 to 79.8% on March 1, 2022 under the baseline scenario of no further regulatory action.



COVID-19 Cases, Deaths, and Hospitalizations Among U.S. Adults

The IHME projections include estimates for infections, new hospital admissions, and deaths at a population level. Several adjustments are necessary to convert these population-level estimates to estimates appropriate for the Head Start staff population characteristics. Specifically, we adjust for the age distribution and vaccine coverage rates of Head Start staff. We discuss these adjustments in the narrative contained in the next two sections.

We generate projections of daily cases by multiplying IHME's projections of daily infections with its daily estimates of the infection detection ratio.[102] Over the period covering November 19, 2021 to March 1, 2022, the estimated infection detection ratio varies between 0.4693 and 0.4993, suggesting that, on any particular day, measured COVID-19 cases likely represent between 47% and 49% of the total COVID-19 infections. We assume that this measure is consistent with the CDC's case definition.[103] We acknowledge the importance of these additional infections that are not confirmed cases but focus on the metric of confirmed COVID-19 cases, which is more comparable with other sources of data used in this analysis.

We make several initial adjustments of the IHME projections, which cover the entire U.S. population, to generate forecasts that are limited to the adult population. Using CDC COVID-19 line-level case surveillance data that cover July 1-September 30, 2021, we estimate that 21% of COVID-19 cases were individuals aged < 18 years.[104] We adjust the total population case projections by this percentage to capture only adult cases. We follow the same procedure for mortality: CDC case surveillance data indicate that 0.1% of COVID-19 deaths were individuals aged < 18 years. We adjust the total population death projections by this percentage to capture only adult deaths.[105] We follow the same

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[102] http://www.healthdata.org/special-analysis/covid-19-estimating-historical-infections-time-series.

[103] https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/.

[104] Calculation based on CDC COVID-19 Line level case surveillance data, HHS Protect. 1,414,206/6,589,127 ≈ 0.21. This share is somewhat higher in recent months than in earlier periods. For all documented COVID-19 cases through September 30, 2021, the share is 14% (4,461,790/31,537,748 ≈ 0.14). Accessed October 8, 2021.

[105] Calculation based on data extracted from https://covid.cdc.gov/covid-data-tracker/#demographics. 637/567,704 ≈ 0.001. Accessed October 3, 2021.

procedure for hospitalizations: CDC COVID-NET data on laboratory-confirmed COVID-19 associated hospitalizations indicate that 1.9% of COVID-19 hospitalizations were individuals aged < 18 years.[106] We adjust the total population hospital admission projections by this percentage to capture only adult hospital admissions. We note that the hospitalization data provide more limited coverage than data on cases and deaths. This adjustment assumes that the distribution of hospitalizations by age nationally are similar to the underlying data. We believe this assumption is more justified, in the context of this analysis, than not performing an adjustment.

Figure 2 presents the IHME projections of daily infections, cases, and our estimates of adult cases. Figure 3 presents the IHME projection of daily excess deaths and reported deaths. This analysis focuses on the projections of reported deaths, which are more comparable with other data sources used in this analysis. Figure 4 presents the IHME projections of daily new hospital admissions and adjusted estimates for adult cases.

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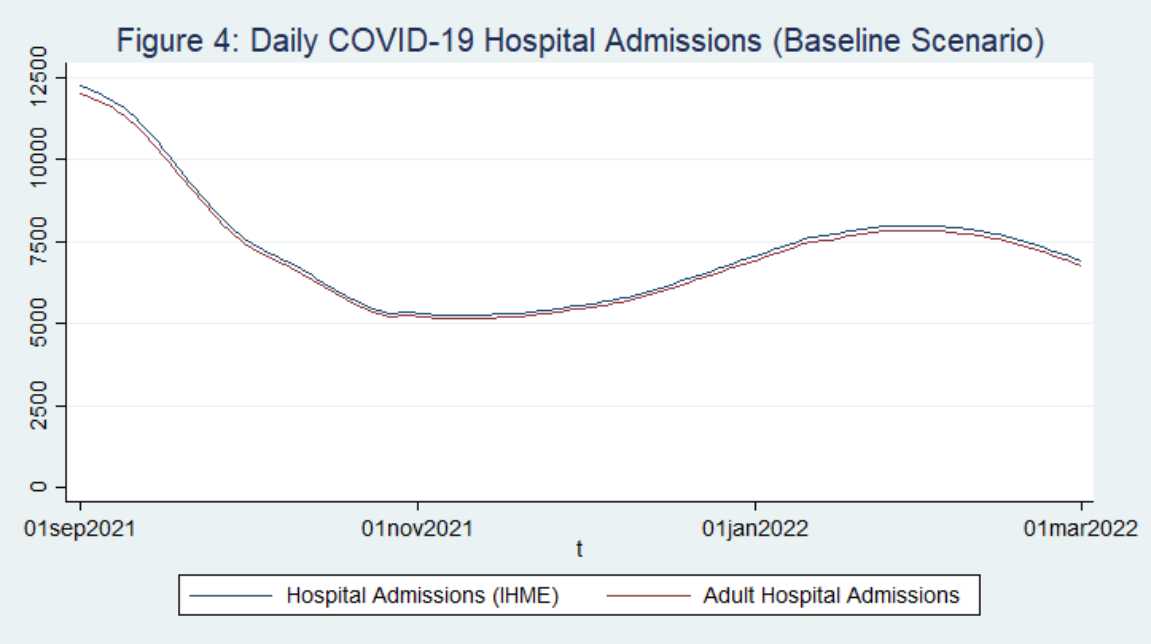
[106] Calculation based on COVID-19-Associated Hospitalization Surveillance Network, Centers for Disease Control and Prevention. https://gis.cdc.gov/grasp/covidnet/COVID19_5.html. 4,228/220,539 ≈ 0.019. Accessed on October 3, 2021.


Figure 2: Daily Infections and Cases (100,000s) (Baseline Scenario)
0
.5
1
1.5
2
2.5
3
3.5
01sep2021
01nov2021
01jan2022
01mar2022
t
Infections (IHME)
Cases (IHME)
Adult Cases

Figure 3: Daily Deaths (Baseline Scenario)
0
1000
2000
3000
01sep2021
01nov2021
01jan2022
01mar2022
t
Excess Deaths (IHME)
Reported Deaths (IHME)



COVID-19 Cases, Deaths, and Hospital Admissions Among Head Start Staff

Head Start staff differ from the general U.S. adult population level in several ways. First, the size of the population is much smaller. Using the IHME total population estimate of about 328 million, and a Census estimate of the population share of adults of about 78%,[107] we compute a total of 255 million adults. The 273,000 Head Start staff represent about 0.1% of total adults. As an initial adjustment, we adjust the baseline scenario estimates of daily cases, deaths, and hospital admissions downward to reflect the population under the scope of the interim final rule.

If Head Start staff had a COVID-19 risk profile that matched the adult population, no further adjustments would be necessary; however, as described above, a higher share of Head Start staff are fully vaccinated than the adult population as a whole, and we expect

[107] https://www.census.gov/popclock/data_tables.php?component=pyramid.

this trend to continue through the time horizon of the baseline scenario of this analysis. To properly account for the risk reductions to Head Start staff attributable to higher vaccination rates, we perform an adjustment based on published estimates of the incidence rate ratios (IRRs) that compare outcomes for unvaccinated and vaccinated persons at a population level, which provide a measure of vaccine effectiveness.[108]

This CDC study reports averaged weekly, age-standardized IRRs for cases, hospitalizations, and deaths, among persons who were not fully vaccinated (simplified later by describing these as "unvaccinated") compared with those among fully vaccinated persons. The IRRs suggest that vaccinated individuals experienced a significantly reduced risk of infection, hospitalization, and death, including during a period when Delta became the most common variant. For the June 20-July 17, 2021 period, the point estimates of the average weekly IRRs for all ages were 4.6 for cases, 10.4 for hospitalizations, and 11.3 for deaths. For individuals between ages 18 and 49 years, these estimates are 4.5 for cases, 15.2 for hospitalizations, and 17.2 for deaths. For individuals between ages 50 and 64 years, these estimates are 4.9 for cases, 10.9 for hospitalizations, and 17.9 for deaths. For individuals aged ≥ 65 years, these estimates are 4.6 for cases, 7.6 for hospitalizations, and 9.6 for deaths.

The IRR of 4.6 for cases means that vaccination offers strong protection against COVID-19 and that fully vaccinated people had about a five-fold reduction in risk of infection

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[108] Scobie HM, Johnson AG, Suthar AB, et al. (2021). "Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4-July 17, 2021." Morbidity and Mortality Weekly Report 2021;70:12841290. DOI: http://dx.doi.org/10.15585/mmwr.mm7037e1.

compared with people not fully vaccinated. These IRR estimates cover adults and are standardized to match the U.S. adult population. They are calculated by dividing average weekly incidence on a per capita basis among unvaccinated individuals by the incidence among fully vaccinated individuals. For example, the study calculates the IRR for cases by dividing 89.1 cases per 100,000 unvaccinated individuals by 19.4 cases per 100,000 vaccinated individuals.[109]

For comparison, the CDC study underlying these estimates also reports higher measurements of the IRR during an earlier time period, covering April 4-June 19, 2021. Specifically, the comparable IRR estimates were 11.1 for cases, 13.3 for hospitalizations, and 16.6 for deaths. The study does not disentangle the changes in the IRR measurements across these time periods that that are attributable to the highly transmissible Delta variant or other factors, such as the potential decline in vaccine effectiveness as the time since vaccination increases. Although the IRRs are unlikely to remain constant over time, the estimates corresponding to the June 20-July 17, 2021 period represent the best available estimates of the IRR for the time horizon of this analysis.

We also generate IRR estimates specific to the Head Start teacher population. These estimates reflect differences in the age distribution of Head Start teachers rather than observational data on COVID-19 cases, since ACF does not collect this information. To generate these estimates , we pair the age-specific IRR estimates with the corresponding age range for Head Start teachers. ACF data indicates that 10.4% of Head Start teachers are ages 18-29 years; ages 30-39 years, 29.6%; ages 40-49 years, 26.7%; ages 50-59

[109] 89.1 / 19.4 ≈ 4.6.

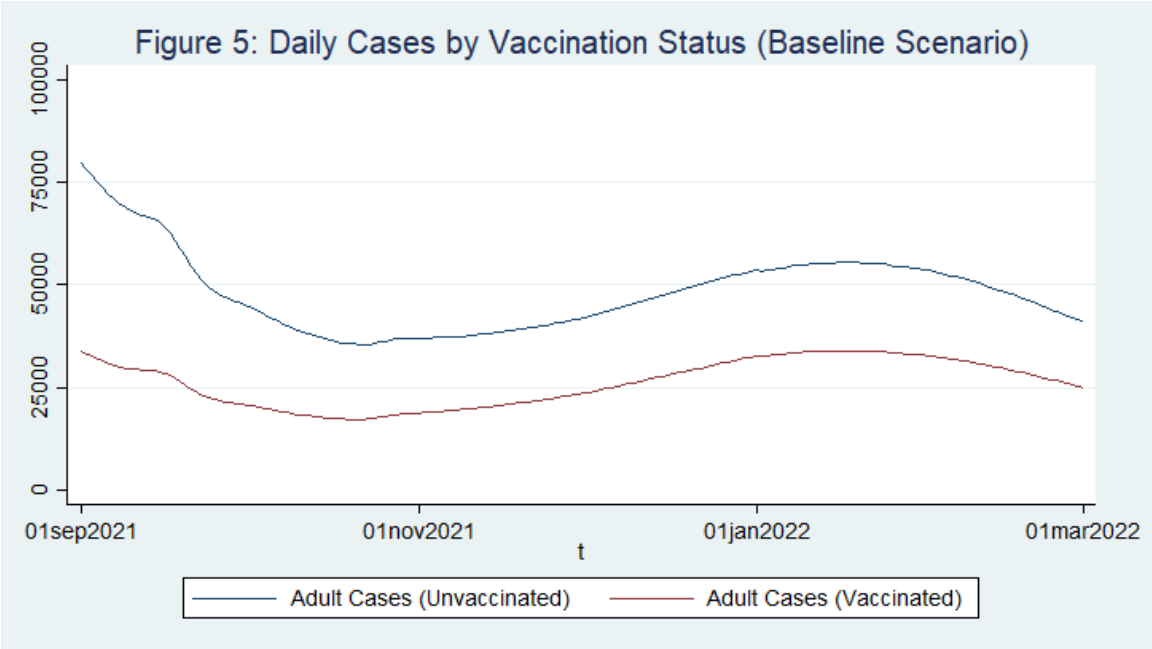
years, 21.7%; and ages >60 years, 11.6%.[110] For the purposes of this analysis, we assume that half of Head Start teachers 60 years and older are ages 60-64 years, and half are ages >65 years. Table 2 presents the central estimates of the age-standardized IRRs for cases, hospitalizations and deaths for the adult population, as reported in the CDC study, and IRRs for the same outcomes, but standardized for the age profile of Head Start teachers. We later apply these estimates, which reflect the Head Start teacher age profile, for a broader population of Head Start staff.

Table 2. Incidence Rate Ratios for Adults and Head Start Teachers

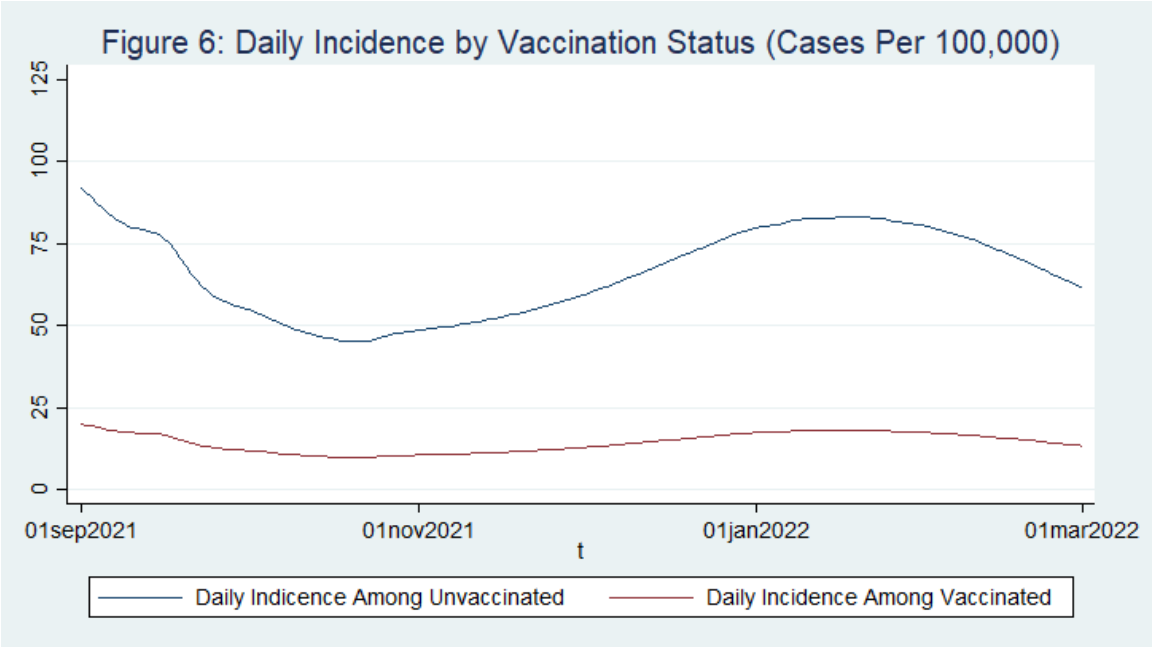
Age Range (years)	Share of Teachers	Case IRR	Hospitalization IRR	Death IRR
18-29	10.4%	4.5	15.2	17.2
30-39	29.6%	4.5	15.2	17.2
40-49	26.7%	4.5	15.2	17.2
50-59	21.7%	4.9	10.9	17.9
60-64	5.8%	4.9	10.9	17.9
65+	5.8%	4.6	7.6	9.6
Adults		4.6	10.4	11.3
Head Start		4.6	13.6	17.0

[110] Doran, Elizabeth, Natalie Reid, Sara Bernstein, Tutrang Nguyen, Myley Dang, Ann Li, Ashley Kopack Klein, Sharika Rakibullah, Myah Scott, Judy Cannon, Jeff Harrington, Addison Larson, Louisa Tarullo, and Lizabeth Malone (2021). A Portrait of Head Start Classrooms and Programs in Spring 2020: FACES 2019 Descriptive Data Tables and Study Design, OPRE Report # 2021-215, Washington, DC: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services. Pending Publication.

By adopting the adult age-standardized IRR estimates, we are able to disaggregate COVID-19 cases among unvaccinated individuals from cases among vaccinated individuals. Figure 5 presents these estimates for the adult population.

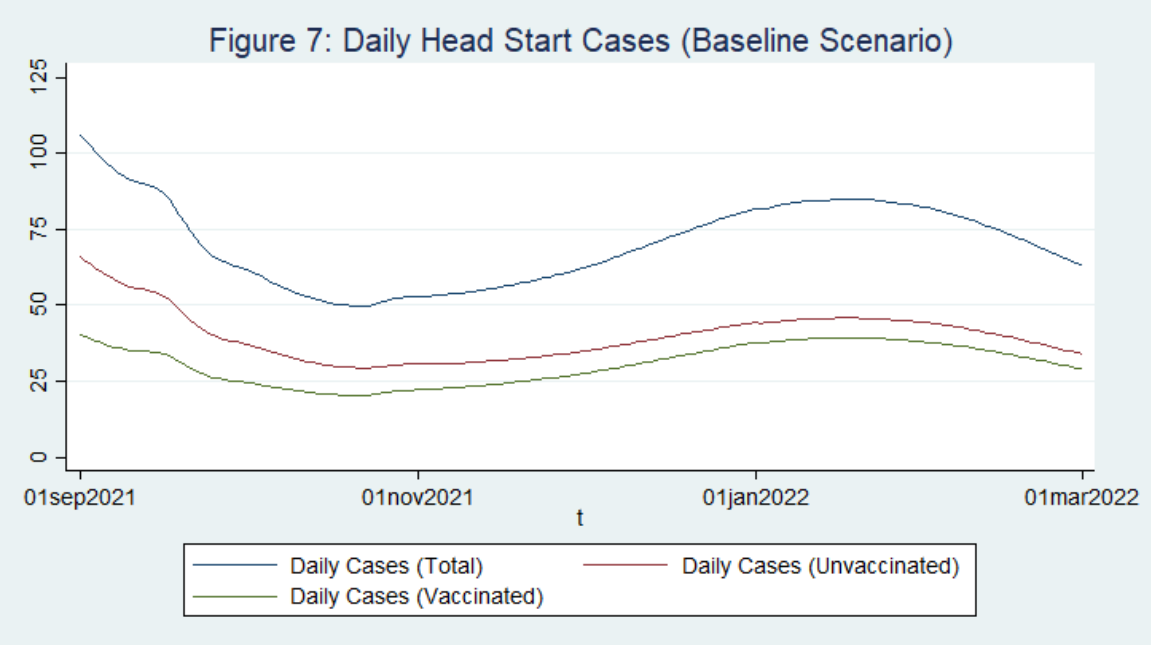


We combine estimates of the daily adult cases among unvaccinated individuals and daily estimates of the unvaccinated adult population to generate daily incidence rates among unvaccinated individuals on a per capita basis. We perform similar calculations to generate daily incidence rates among vaccinated individuals on a per capita basis. Figure 6 reports the daily incidence over time and by vaccination status. These estimates are reported as cases per 100,000 individuals. For the last week in our projections, covering February 23, 2022 to March 1, 2022, the weekly incidence rate for unvaccinated adults is about 446 cases per 100,000, while the weekly incidence rate for vaccinated adults is about 97 cases per 100,000, which is consistent with a 4.6 IRR. This time period corresponds to an adult vaccination rate of 73.8%, for a total adult weekly incidence rate of about 188 cases per 100,000, and a total weekly adult case count of 480,523.



To generate estimates of cases among Head Start staff, we combine the estimates of vaccine uptake from Figure 1, estimates of the daily incidence by vaccination status, applying the IRR measure specific to Head Start staff, with outcomes scaled by the number of Head Start staff. This approach assumes, for the purpose of developing quantitative projections, that daily exposure to COVID-19 among Head Start staff is largely driven by interactions with the public as a whole and that Head Start staff face similar exposure to these risks as other adults. If Head Start staff face greater exposure to these risks than the adult population, such as through routine contact with children who are generally not eligible for a COVID-19 vaccination, this will cause our baseline estimates of cases, hospitalizations, and deaths among Head Start staff to be downward biased. This would similarly result in our estimates of the health benefits from increases in vaccine coverage to be downward biased. We project that Head Start staff will experience lower per-capita case counts than the general adult population due to higher rates of vaccination, and a higher IRR rate consistent with the age profile of Head Start staff compared to all adults. Figure 7 presents daily Head Start cases. For the last week in

our projections, covering February 23, 2022 to March 1, 2022, we estimate about 457 total cases, with 246 cases from unvaccinated, and 211 cases from vaccinated Head Start staff. These cases translate to a baseline Head Start weekly incidence rate of about 167 cases per 100,000.



We generate estimates of the Head Start deaths and hospital admissions using the same approach as we describe for cases. We adopt IRR estimates specific to the Head Start staff population of 17.0 for deaths and an IRR of 13.6 for hospitalizations. These IRRs indicate that the COVID-19 vaccines provide even stronger protection against COVID-19 associated hospitalization and death than against infections. We perform adjustments to the adult incidence rates that are intended to control for deaths and hospital admissions that are concentrated in older age groups than we observe among Head Start staff.

Using CDC surveillance data through October 3, 2021, we observe that, among the 567,704 COVID-19 deaths in the United States for which age data are available, 319,311

deaths are among individuals ≥ 75 years. While the Head Start workforce includes a number of older individuals, very few are ≥ 75 years. Head Start data indicate that 11.6% of teachers are age 60 years or older, compared to the general population share of 22.7%. We anticipate that almost all of the Head Start teachers age 60 years or older are between age 60 and 74 years, and assume this is also true for the broader Head Start staff population. Therefore, we adjust the adult death incidence rate to exclude deaths among individuals ≥ 75 years. This adjustment reduces the baseline forecast for Head Start deaths downwards by about 56%.[111] Older individuals are also hospitalized at higher rates than younger peers, but this difference is less pronounced than for deaths. Among laboratory-confirmed COVID-19-associated hospitalizations for which age data are available, about 43% are individuals ≥ 65 years[112], an age subgroup representing about 16.5% of the total population. Since only 5.8% of Head Start staff are individuals ≥ 65 years, we reduce the total population baseline forecasts for hospitalizations by about two thirds[113] of 43%, or about 28%[114], since we expect a significant share of these hospitalizations to be among individuals older than most Head Start staff.

Figure 8 reports daily Head Start deaths attributable to COVID-19 under the baseline scenario. For the entire period of the baseline scenario, we anticipate fewer than one COVID-19 related death per day among Head Start staff. For the last week in our projections, covering February 23, 2022 to March 1, 2022, we estimate 2.9 weekly deaths out of the total Head Start staff population of 273,000. To provide additional context, this

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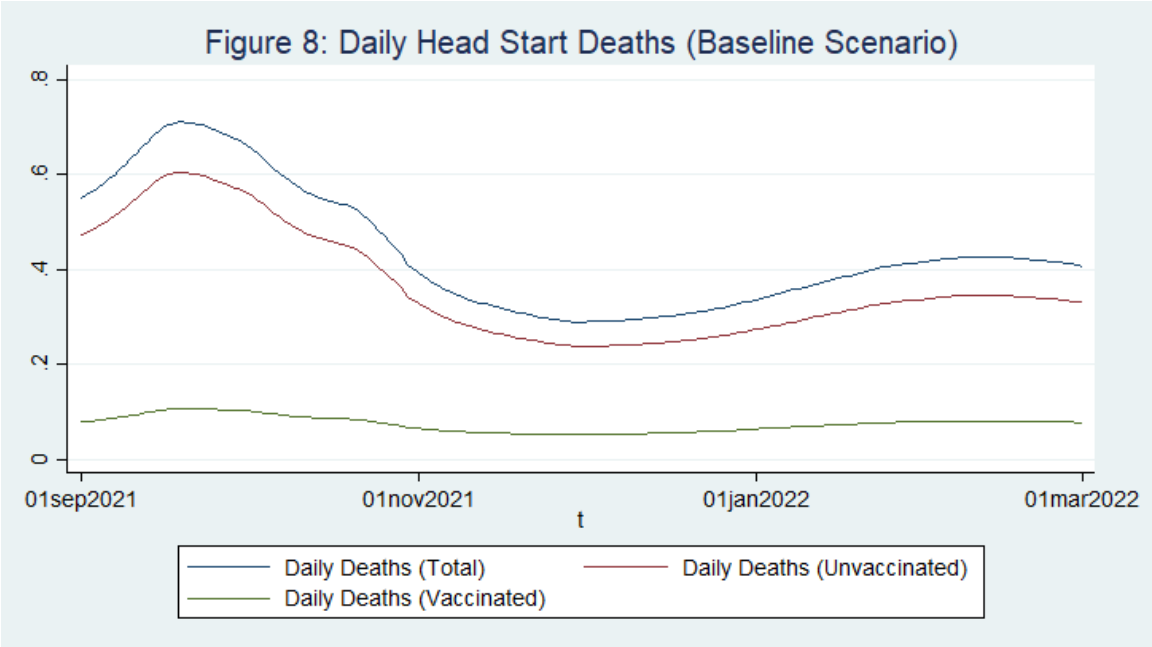
[111] 319,311/(567,704-637) ≈ 0.56.

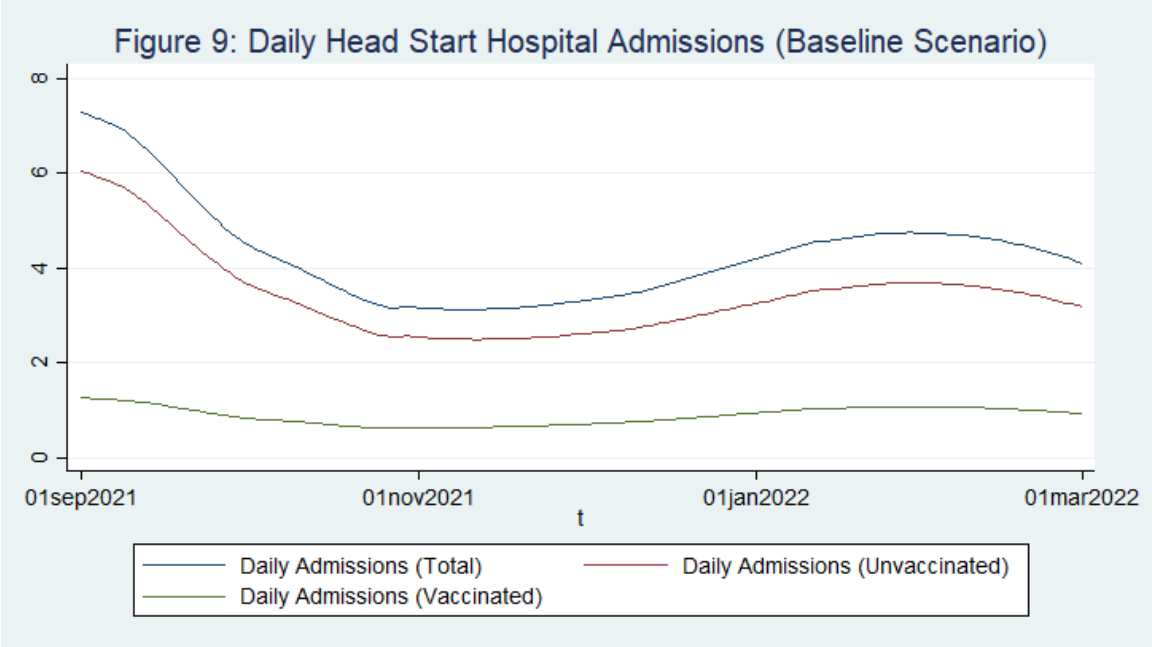
[112] 92,960/(220,539-4,228) ≈ 0.43.

[113] 0.058/0.165 ≈ 0.35. 1-0.35 = 0.65.

[114] 0.43*0.65 ≈ 0.28.

is a weekly incidence rate of 1.06 deaths per 100,000 individuals. The comparable adult weekly incidence rate is about 3.18 deaths per 100,000 individuals. Figure 9 reports daily Head Start hospital admissions. For the last week in our projections, we estimate 29 hospital admissions for a weekly incidence rate of 10.8 per 100,000.





Head Start Program Operating Status and Staffing

The Office of Head Start has tracked the operating status of programs since the onset of the pandemic. In March and April of 2020, more than 90% of programs closed all in-person operations. By August of 2020, 21% of programs had reopened for in-person services, 26% remained closed for in-person services due to COVID-19, and the remainder of programs were closed for summer months as regularly scheduled. In December 2020, data show the highest combined percentage (67%) of Head Start centers operating as solely virtual/remote or as hybrid, with an additional 5% of centers closed. Together, these centers account for over 13,500 centers nationwide. This represents many working parents for whom unpredictable closures and transitions to virtual learning come at a cost, present difficult decisions between employment and child care responsibilities, and major financial impacts on their household.

Most recently, July 2021 data show that 2% of centers were closed due to COVID-19, 14% of centers were operating virtual/remote, and 44% of centers were operating in a hybrid status, which includes programs that are alternating between in-person services, virtual or remote services, or some combination of the two. Only 35% of centers were operating fully in-person. We do not have comparable data for about 5% of centers.[115] While closures have declined, the majority of Head Start centers are still operating in virtual/remote or a hybrid status. We adopt these estimates as providing a reasonable representation of the operating status of Head Start centers under the baseline scenario of no regulatory action. These estimates are intended to represent a steady state of overall operating status under the baseline scenario rather than indicating that any particular

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[115] We are missing data on about 5% of centers. For the purposes of this analysis, we assign an operating status to these centers in proportion with the centers for which we have complete data.

center will remain in its current status without regulatory action. Table 3 presents the in-person days per week by center status. For these estimates, we adopt several assumptions: (1) the average number of staff and children served by each center does not vary by center status; (2) that centers in hybrid operating status meet in person 2.5 days per week, on average; and (3) that centers in fully in-person status meet in person 5.0 days per week, on average. For the purpose of this analysis, we also assume that the centers with unknown operating status are distributed evenly across each center status category. For our estimate of the total number of children, we use "funded enrollment," which refers to the number of children and pregnant people that are supported by federal Head Start funds in a program at any one time during the program year, but reduce this estimate by 1% to account for pregnant people enrolled in Early Head Start.[116]

Table 3. In-Person Days Per Week by Center Status

Center Status	**Centers**	**Staff**	**Children**	**In-Person Days Per Week**	**In-Person Days Per Week**	
					Staff	**Children**
Closed	414	5,453	17,264	0.0	0	0
Virtual/Remote	3,013	39,698	125,679	0.0	0	0
Hybrid	9,667	127,391	403,305	2.5	318,477	1,008,264
Fully In-Person	7,623	100,458	318,041	5.0	502,292	1,590,204
Total	20,717	273,000	864,289	N/A	820,769	2,598,467

Early care and education providers, including Head Start programs, are currently experiencing significant challenges in recruiting and retaining staff that are attributable to

[116] https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/no-search/hs-program-fact-sheet-2019.pdf

the COVID-19 pandemic and general trends in early care and education labor markets. These ongoing challenges, which represent the baseline scenario and are not attributable to the interim final rule, are difficult to quantify; however, the section on Costs expands on this discussion. This discussion includes a range of estimates to inform how the requirements in this rule could exacerbate this issue for certain programs, which could include programs not being able to fully staff their classrooms.

E. Impact on Vaccine Coverage

The key parameter underlying the estimated benefits and costs of the interim final rule is the incremental impact on vaccine uptake, which is the difference between the share of individuals who are unvaccinated under the baseline scenario and who are induced to get fully vaccinated under the interim final rule. As we discuss further in the Benefits and Costs sections, higher rates of incremental vaccine uptake are associated with higher benefit estimates, but also lower overall costs. Given the importance of this parameter and its uncertain nature, we perform an analysis of several scenarios for vaccine uptake, and present estimates of the benefits and costs of the interim final rule for each scenario. Each of the scenarios adopt the following timing and simplifying assumptions:

1) For the purposes of this analysis, we adopt November 22, 2021 as the public announcement date of the interim final rule.
2) The effective date of the vaccination requirement is January 31, 2022. We anticipate that some Head Start staff will wait until January 31, 2022 to receive their final vaccination dose.
3) We do not attribute any impact on the rate of fully vaccinated Head Start staff until at least December 6, 2021. The earliest impacts would be among Head Start staff who have received one COVID-19 dose as part of a two-dose series at the time of the public announcement of the interim final rule who are induced by the interim final rule to complete their two-dose series. The latest impacts would be among Head Start staff who receive their final dose on January 31, 2022, who will be considered fully vaccinated two weeks later, on February 14, 2022.
4) The interim final rule describes exemptions from the vaccination requirement. For the purposes of this analysis, we assume that 5% of total Head Start staff will seek and be

granted an exemption from the vaccination requirement.[117] These individuals will not be induced to get fully vaccinated under the interim final rule. This assumption translates to least 13,650[118] Head Start staff who will remain unvaccinated under all vaccine coverage scenarios.

Our upper-bound scenario is based on an observation contained in the HHS *Guidelines for Regulatory Impact Analysis,* which notes that "[i]n most cases, the analysis focuses on estimating the incremental compliance costs incurred by the regulated entities, assuming full compliance with the regulation, and government costs."[119] For the purpose of this analysis, we maintain the assumption that 5% of Head Start staff will seek and be granted an exemption, while the remaining 95% will be fully vaccinated. These represent two of the routes that Head Start staff can demonstrate full compliance with the interim final rule. We note that the HHS *Guidelines for Regulatory Impact Analysis* further recommend that "[a]nalysts should consider the uncertainty associated with an assumption of full compliance and provide analysis of alternative assumptions, as appropriate."

Our lower-bound scenario adopts an estimate drawn from an Issue Brief published by the HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE), which finds that "[a]s of August 2021, approximately 30% of U.S. adults are unvaccinated;

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[117] This estimate is consistent with an assumption discussed in the Preamble of the Emergency Temporary Standard recently issued by the Department of Labor's Occupational Safety and Health Administration. "OSHA estimates that some 5% of employees may have a medical contraindication or request an accommodation from the rule's requirements for disability or sincerely held religious belief reasons." https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard.

[118] 0.05 * 273,000 = 13,650.

[119] https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis

among these, approximately 44% may be willing to get vaccinated against COVID-19."[120] This published finding is based on an analysis using survey data for Week 33 of the Household Pulse Survey (June 23 - July 5, 2021). We perform an identical calculation using Week 39 (September 29 - October 11) survey responses, which results in a lower estimate of 33.4%. We assume that 33.4% of the unvaccinated individuals will be induced to get fully vaccinated by this time under the policy scenario. Under this scenario, about 86.6% of Head Start staff are fully vaccinated by February 14, 2022.

These estimates are from a nationally representative survey of households, but are broadly consistent with responses from another survey specific to U.S. child care providers.[121] In this survey, which informs our baseline forecast of Head Start staff vaccine coverage, overall vaccine uptake among U.S. child care providers was 78.2%. Among unvaccinated survey respondents, including child care providers not affiliated with Head Start, the authors note that "only 5.0% were 'absolutely certain' that they would get vaccinated in the future, 6.9% were 'very likely,' 28.2% were 'somewhat likely.'" These percentages, which sum to 40.1%, suggest substantial room for additional vaccine uptake among child care providers, even though rates significantly exceeded the general population at the time of the survey. As a sample calculation, if 40.1% of the 21.8% of unvaccinated survey respondents get vaccinated, this would increase the overall vaccine uptake among U.S. child care providers from 78.2% to 86.9%. This estimate is

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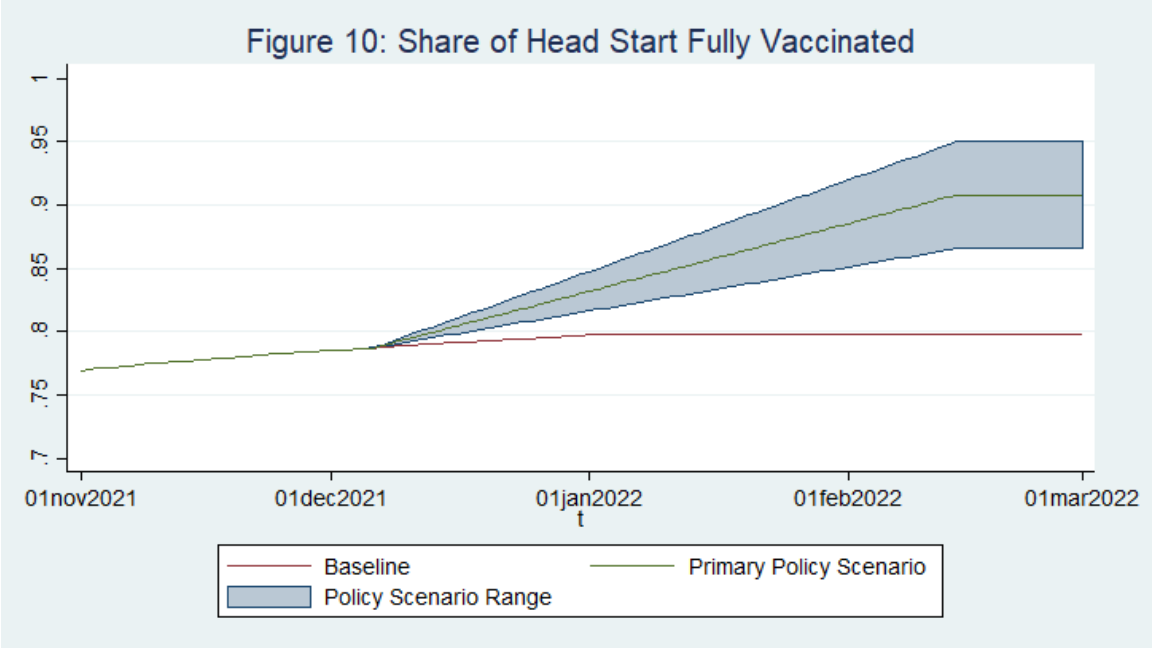
[120] https://aspe.hhs.gov/reports/unvaccinated-willing-ib

[121] Patel KM, Malik AA, Lee A, et al. (2021). "COVID-19 vaccine uptake among US child care providers." *Pediatrics*; doi: 10.1542/peds.2021-053813.

slightly above our lower-bound estimate of vaccine coverage for Head Start staff under the interim final rule.

We anticipate that the vaccination requirement will induce more unvaccinated Head Start staff to get fully vaccinated than the lower-bound vaccine-uptake estimates suggest. For our primary scenario, we adopt the midpoint vaccine coverage rate between our lower- and upper-bound scenarios, and project overall vaccine coverage of 90.8% among Head Start staff by February 14, 2022.

Figure 10 presents our forecasts of the share of Head Start staff who are fully vaccinated under the baseline scenario, and our range of policy scenarios. For our baseline scenario, we estimate the share who are fully vaccinated of 79.8%, or 217,879 fully vaccinated Head Start staff out of 273,000 total staff. We estimate a range of estimates under of our policy scenario between 86.6% and 95.0%, for an incremental vaccine uptake of between 6.8% and 15.2%. For our primary policy scenario, we estimate overall vaccine coverage of 90.8%, for an incremental vaccine uptake of 11.0%. Under the primary scenario, we estimate 247,833 fully vaccinated Head Start staff, and an incremental 29,953 staff fully vaccinated attributable to the interim final rule.



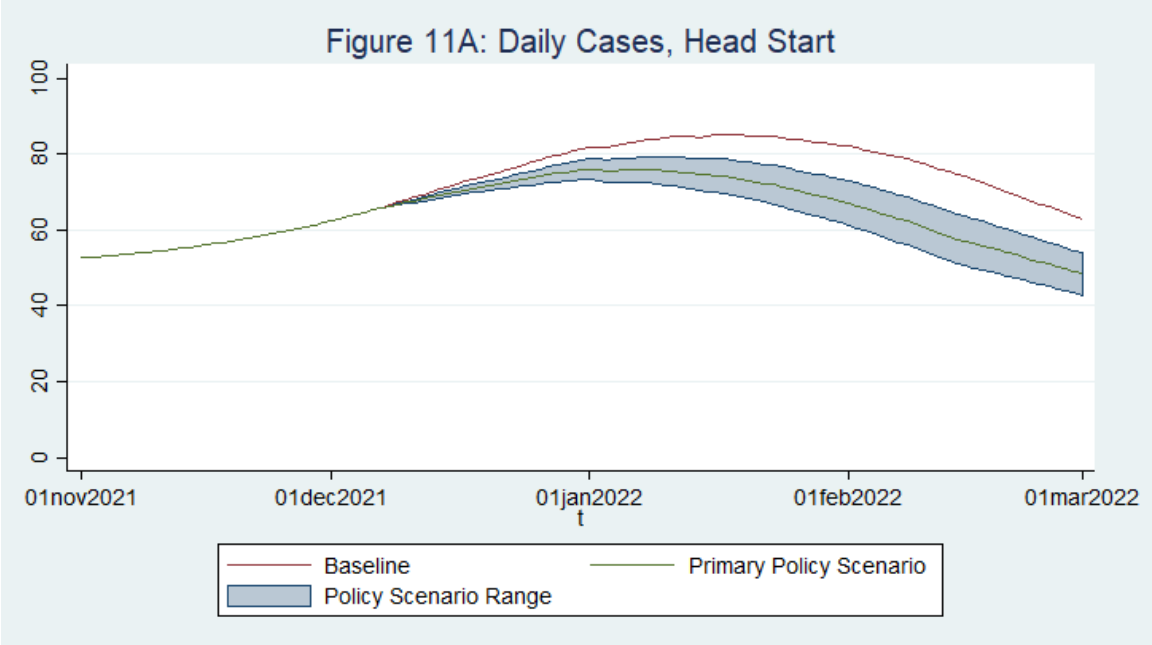
E. Benefits of the Rule

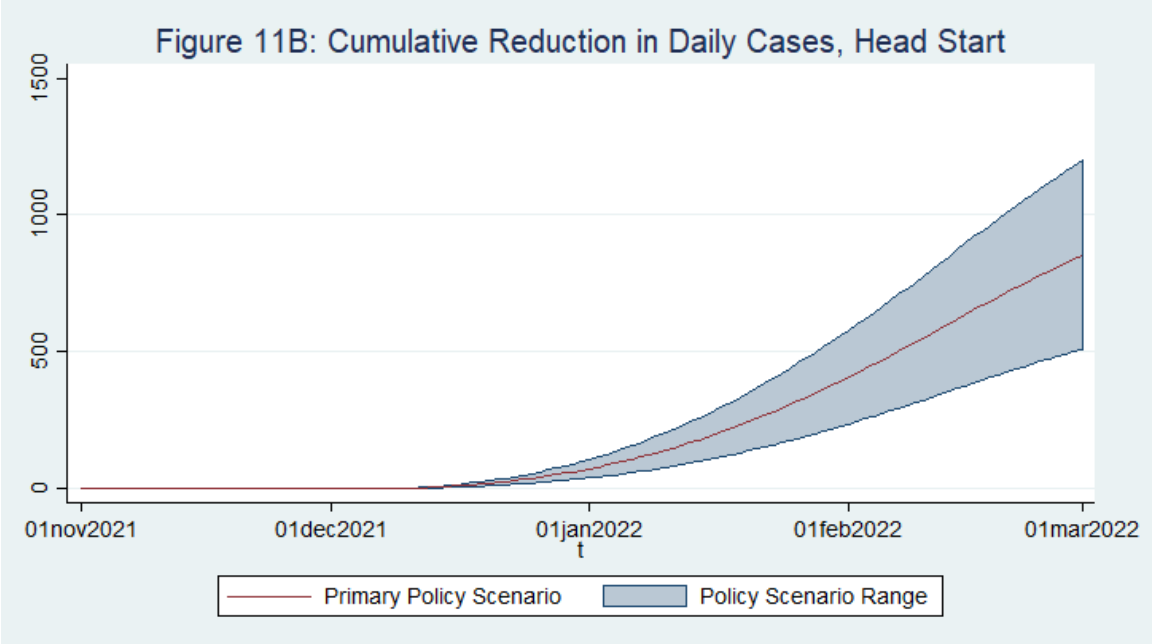
We follow identical procedures outlined in the baseline section to generate forecasts of COVID-19 cases, deaths, and hospitalizations that are consistent with a range of vaccine coverage estimates under the policy scenarios. We estimate the likely impacts of the interim final rule by calculating the difference between the measurable COVID-19 outcomes under the policy scenarios against the baseline scenario described in the previous section.

Reduction in Cases Among Head Start Staff

Figure 11A presents our estimates of the daily COVID-19 cases among Head Start Staff under each scenario. The baseline scenario corresponds to the estimates presented in Figure 7 in the previous section. Figure 11B presents the cumulative reduction in cases over time that are attributable to the interim final rule under the vaccine coverage scenarios. Through March 1, 2022, the impact of the interim final rule is cumulative

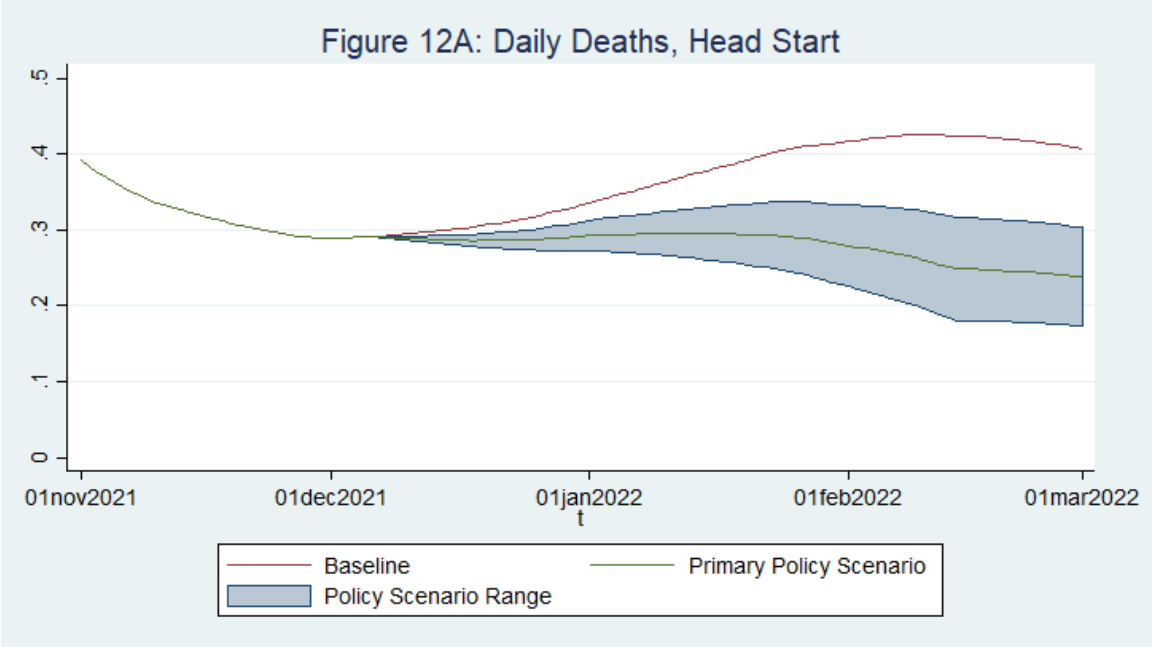
COVID-19 case reductions between 510 and 1,198, which correspond to the range of vaccine coverage scenarios.

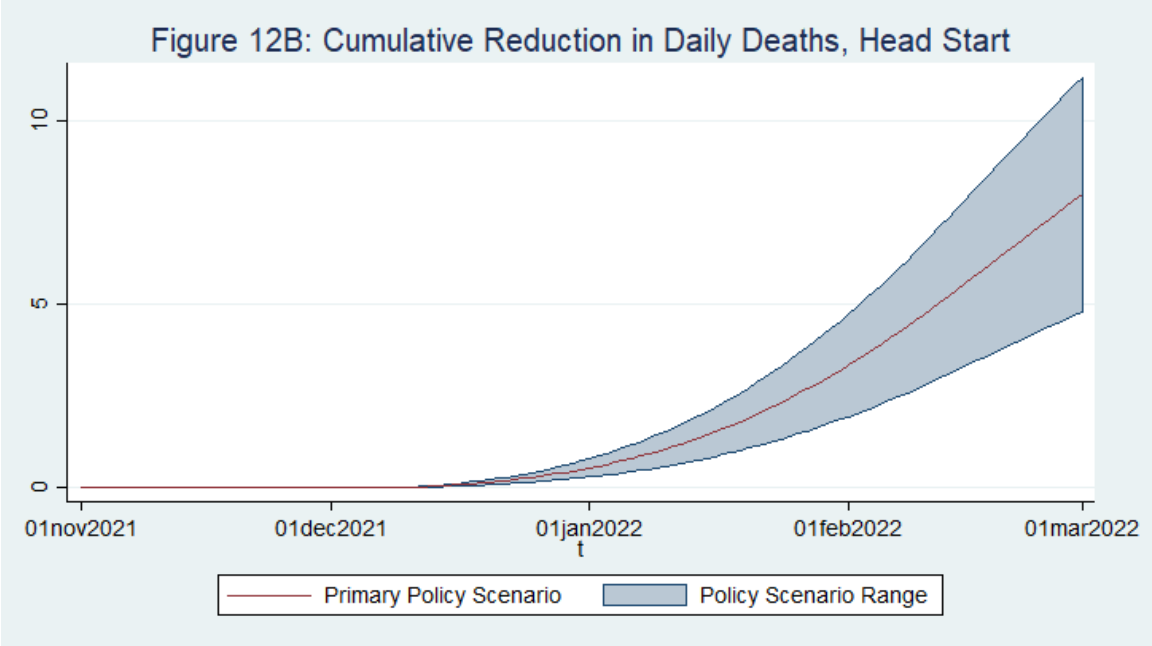




Reduction in Deaths Among Head Start Staff

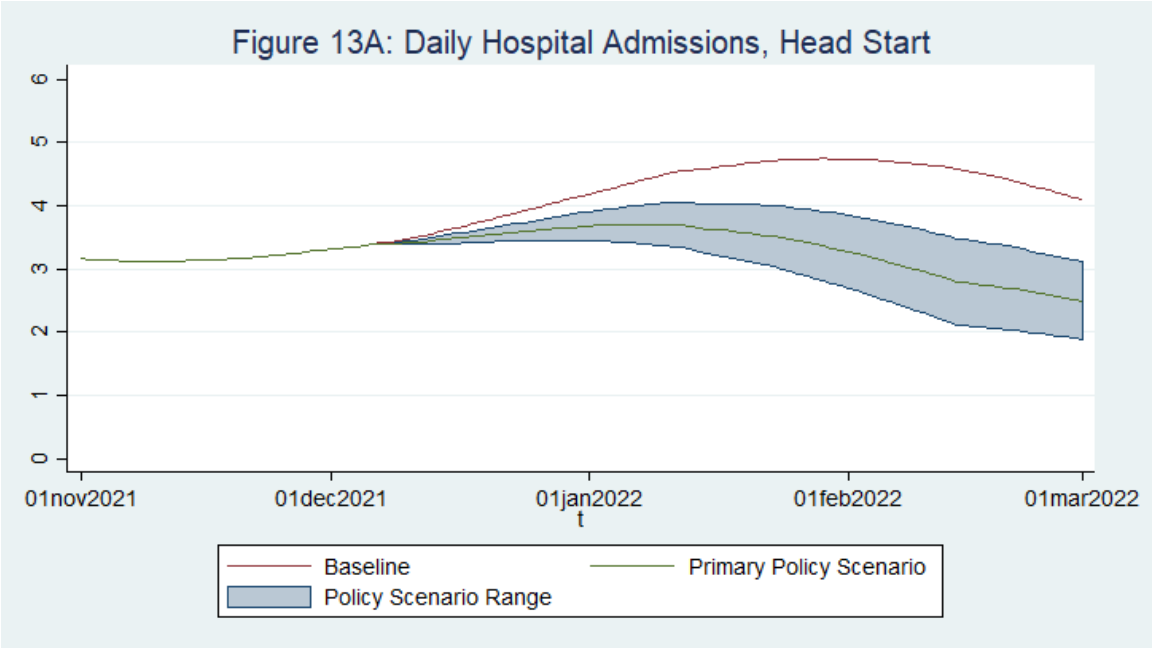
Figure 12A presents our estimates of the daily COVID-19 deaths among Head Start Staff under each scenario. The baseline scenario corresponds to the estimates presented in Figure 8 in the previous section. Figure 12B presents the cumulative reduction in deaths over time that are attributable to the interim final rule under the vaccine coverage scenarios. Through March 1, 2022, the impact of the interim final rule is cumulative COVID-19 mortality reductions between 4.8 and 11.2, which correspond to the range of vaccine coverage scenarios.

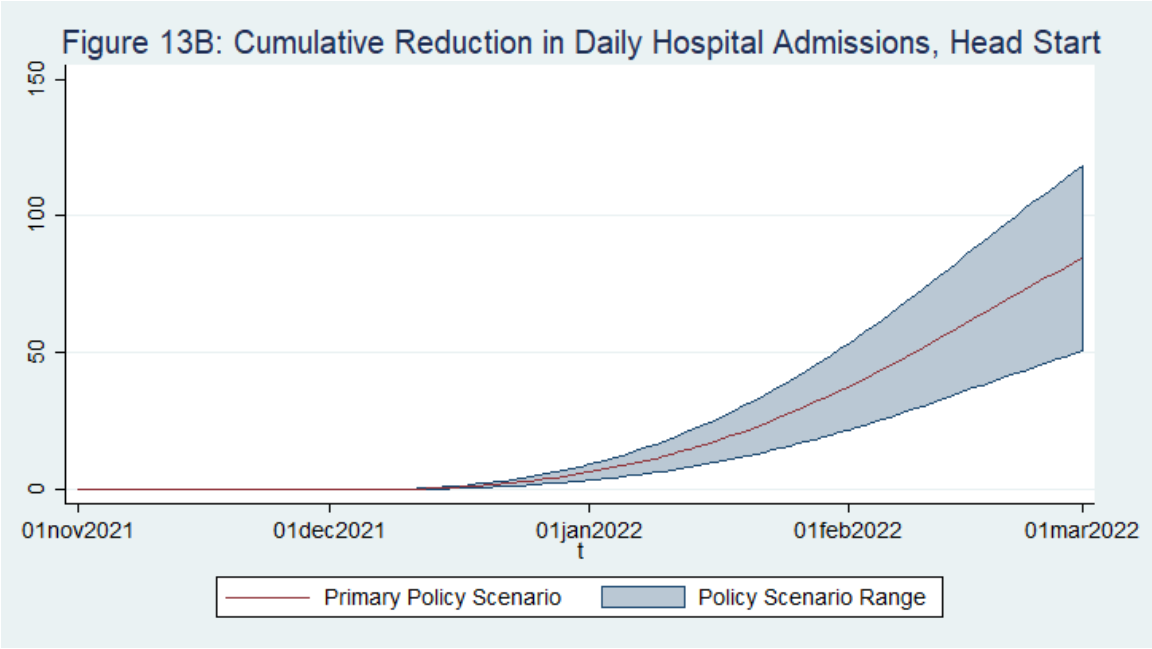




Reduction in Hospital Admissions Among Head Start Staff

Figure 13A presents our estimates of the daily COVID-19 hospital admissions among Head Start Staff under each scenario. The baseline scenario corresponds to the estimates presented in Figure 9 in the previous section. Figure 13B presents the cumulative reduction in hospital admissions over time that are attributable to the interim final rule under the vaccine coverage scenarios. Through March 1, 2022, the impact of the interim final rule is cumulative COVID-19 hospital admission reductions between 51 and 118, which correspond to the range of vaccine coverage scenarios.





Valuing Health Benefits Among Head Start Staff

Table 3 summarizes several measurable improvements in COVID-19 outcomes for Head Start staff that are attributable to the interim final rule. For the baseline scenario of no new regulatory action, and for each of the vaccine coverage scenarios, we report the share of Head Start staff that are fully vaccinated by March 1, 2022, and the

corresponding cumulative cases, deaths, and hospital admissions averted over the time horizon of the analysis.

IHME's daily projections for U.S. hospital admissions include about 35% that result in intensive care unit (ICU) admissions. Head Start hospital admissions estimates are adjusted downwards to reflect a lower rate of hospitalization among younger individuals. We similarly expect the share of hospitalizations that include an ICU admission to be lower for Head Start staff compared to the general adult population; however, we are not aware of an estimate that is directly transferable, and adjust this estimate of the share of hospital admissions that result in an ICU admission down by half. We believe this assumption is more justified, in the context of this analysis, than not performing an adjustment. *Assuming about 17.5% of the cumulative hospital admissions result in an ICU admission, we estimate 76 ICU admissions under the baseline scenario, and between 55 and 67 ICU admissions under the interim final rule, depending on the vaccine coverage scenario. Therefore, we measure a reduction of between 9 and 21 ICU admissions under the interim final rule. We follow the same approach to calculate non-ICU hospital admissions for the remaining 82.5% of total hospital admissions.*

Table 4. Cumulative Impacts Among Staff by Vaccine Coverage Scenario

Outcome	**Baseline Scenario**	**Vaccine Coverage Scenario**			**Difference**		
		Low	**Primary**	**High**	**Low**	**Primary**	**High**
Fully Vaccinated Rate	79.8%	86.6%	90.8%	95.0%	6.8%	11.0%	15.2%
Cases	7,724	7,214	6,870	6,526	-510	-854	-1,198
Deaths	37.3	32.4	29.3	26.1	-4.8	-8.0	-11.2
Hospital Admissions	428	377	343	309	-51	-84	-118

Non-ICU	352	310	282	255	-42	-69	-97
ICU	76	67	61	55	-9	-15	-21

Valuing risk reductions associated with regulations that address the COVID-19 presents major challenges. We adopt an approach to monetize the cumulative cases, deaths, and hospitalizations averted under the interim final rule by closely following the methodology described in an ASPE report on "Valuing COVID-19 Mortality and Morbidity Risk Reductions in U.S. Department of Health and Human Services Regulatory Impact Analyses."[122] *This paper addresses these challenges by summarizing the impacts of COVID-19 on health and longevity, describing the conceptual framework for valuation, investigating some of the available valuation research (as of March, 2021), and discussing the implications.*[123] *We note that the impact of the virus is rapidly evolving, and new data are continually emerging. We have reviewed the assumptions and evidence contained in this report and conclude that the quantitative estimates remain useful for assessing the impacts of this interim final rule.*

Valuing these risk reductions using the estimates contained in the ASPE report requires assumptions that map the non-fatal risk reductions quantified in Table 4 into "mild," "severe," and "critical" case-severity categories. These categories are characterized by common symptoms experienced for an acute phase and post-acute phase. Below, we

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[122] https://aspe.hhs.gov/reports/valuing-covid-19-risk-reductions-hhs-rias

[123] Additional relevant citations not contained in the report include Viscusi, W.K. Pricing the global health risks of the COVID-19 pandemic. J Risk Uncertain 61, 101–128 (2020). https://doi.org/10.1007/s11166-020-09337-2 and Viscusi WK. Economic lessons for COVID-19 pandemic policies [published online ahead of print, 2021 Mar 4]. South Econ J. 2021;10.1002/soej.12492. doi:10.1002/soej.12492.

reference the description of each case-severity category from Table 3.2 Common Symptoms of Nonfatal COVID-19 Cases by Severity Level of the ASPE Report.[124]

For the acute phase of a critical case, "[i]ndividuals will have early symptoms similar to those of mild and severe disease. Individuals may quickly progress to respiratory failure and may also have septic shock, encephalopathy (brain disease), heart disease or failure, coagulation dysfunction (inability of blood to clot normally), and acute kidney injury. Organ dysfunction can be life-threatening. Individuals with critical disease often receive prolonged mechanical ventilation." For the post-acute phase, "[i]ndividuals are likely to have long-term physical and cognitive impairment similar to other critical illnesses." We initially assign the 9 to 21 averted ICU admissions to the critical case category, but we reduce these estimates by the number of deaths averted. This approach avoids the potential for double counting, since the underlying VSL estimates likely include the willingness-to-pay to avoid some morbidity prior to death.

The ASPE Report discusses these considerations in greater detail, noting that "COVID-19 deaths are generally preceded by about two weeks of symptoms, including fever, shortness of breath, high respiratory rate, and cough. They may also involve being placed on mechanical ventilation in a medically induced coma." This is in contrast to "[t]he studies that underlie the HHS VSL estimates, [which] focus largely on occupational risks that lead to relatively immediate death from injury." Therefore, we explore the sensitivity of the overall results to this approach. Including the value of a critical case to the value of the mortality reductions for these individuals prior to death would increase the total monetized health benefits by between $8.7 million and $20.3

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[124]https://aspe.hhs.gov/reports/valuing-covid-19-risk-reductions-hhs-rias. Table 3.2 appears on page 35.

million, depending on the vaccine coverage scenario. We do not include these estimates in the summary of monetized benefits.

For the acute phase of a severe case, "[i]ndividuals will have early symptoms similar to those of mild disease, such as fever and cough, which may be accompanied by gastrointestinal symptoms, such as diarrhea. The disease continues to progress for over a week. Dyspnea (shortness of breath), high respiratory rate, and/or blood oxygen saturation of ≤93 percent occur. Individuals typically have pneumonia and require supplementary oxygen. Individuals with severe disease should be hospitalized." For the post-acute phase, "[i]ndividuals may have post-acute symptoms, such as cough, shortness of breath, fatigue, and pain." We assign the 42 to 97 non-ICU hospital admissions averted to the severe case category.

For the acute phase of a mild case, "[i]ndividuals will have symptoms of acute upper respiratory tract infection, which may include fever, fatigue, myalgia (muscle aches), cough, and sore throat. Some cases may have digestive symptoms, such as nausea, abdominal pain, and diarrhea. Loss of taste and smell are common symptoms. Individuals may have mild pneumonia (infection of the lungs), and some may have wheezing or dyspnea (shortness of breath) but blood oxygen saturation remains above 93 percent." For the post-acute phase, "[i]ndividuals may have post-acute symptoms, such as cough, shortness of breath, fatigue, and pain." We initially assign the 510 to 1,198 cumulative cases averted to the mild case category, but we reduce these estimates by the corresponding estimates of critical and severe cases to avoid double counting. This yields an estimate of between 460 to 1,080 mild cases averted.

We considered a further adjustment to the estimate range for mild cases to account for the share of cases that are asymptomatic. As noted above, these estimates are derived from projections of measured COVID-19 cases, rather than total COVID-19 infections. Over the period of the analysis, these represent slightly less than half of the total projected infections, including those not confirmed through testing. This means that, while our measure of mild cases likely includes some confirmed cases that are asymptomatic, it does not include some symptomatic COVID-19 infections that are not confirmed through testing. The ASPE report also discusses the potential for "cases that are initially asymptomatic or mildly symptomatic may ultimately lead to impaired health over the longer run," suggesting that the VSC estimates for mild cases may underestimate the full long-run health-related quality of life consequences of an infection. Given the multiple sources and potential direction of the bias, we have determined that it is appropriate to not make an explicit adjustment. However, we have incorporated uncertainty into the main analysis, which includes a range of total cases averted. We also perform a sensitivity analysis for all health benefits monetized in this analysis by applying a range of VSC and VSL estimates.

The mortality and morbidity risk reductions we identify in this regulatory impact analysis accrue to a working-age Head Start staff population. We have taken care to ensure that our estimates of the cumulative cases, deaths, and hospital admissions averted would not be biased upwards due to an overrepresentation of deaths and hospital admissions among individuals older than the typical Head Start staff. Thus, we adopt the population-average VSL and VSC estimates contained in the ASPE report, with a minor adjustment of 0.8% to account for real income growth, since the mortality and morbidity risk reductions occur in 2021 and the underlying estimates are from a 2020 base year.

Table 5A reports the mortality risk reductions attributable to the interim final rule, and the morbidity risk reductions, categorized by case-severity category. We monetize these impacts using a VSL of about $11.5 million, and VSC estimates that vary by case severity. We multiply the risk reductions by the appropriate VSL or VSC estimate to generate estimates of the value of these risk reductions. We sum these to generate a monetized benefit of the health benefits to Head Start staff attributable to the interim final rule under the vaccine coverage scenarios. Using a 3% discount rate, which affects the underlying value per quality-adjusted life year estimate used in the ASPE report to generate the VSC estimates, we report a total value of risk reduction of between $66.0 million and $154.1 million. Table 5B reports the same estimates using a 7% discount rate. Under this discount rate, we report a total value of risk reduction of between $68.2 million and $159.2 million. All estimates are reported using 2020 dollars. These impacts cover the period between the publication date of the interim final rule and March 1, 2022, the last day reported in the IHME projections.

Table 5A. Value of COVID-19 Risk Reductions Among Staff, 3% Discount Rate

Risk Reduction	**Vaccine Coverage Scenario**			**VSL or VSC**	**Value of Risk Reduction ($ millions)**		
	Low	**Primary**	**High**		**Low**	**Primary**	**High**
Mortality Reductions	4.8	8.0	11.2	$11,501,365	$55.2	$92.0	$128.8
Morbidity Reductions							
Mild Cases	459.8	769.8	1,079.7	$5,846	$2.7	$4.5	$6.3
Severe Cases	41.6	69.4	97.2	$13,104	$0.5	$0.9	$1.3
Critical Cases	4.2	7.0	9.8	$1,814,400	$7.6	$12.7	$17.7
Total Value of Risk Reductions					$66.0	$110.1	$154.1

Table 5B. Value of COVID-19 Risk Reductions Among Staff, 7% Discount Rate

Risk Reduction	Vaccine Coverage Scenario			VSL or VSC	Value of Risk Reduction ($ millions)		
	Low	Primary	High		Low	Primary	High
Mortality Reductions	4.8	8.0	11.2	$11,501,365	$55.2	$92.0	$128.8
Morbidity Reductions							
Mild Cases	459.8	769.8	1,079.7	$9,778	$4.5	$7.5	$10.6
Severe Cases	41.6	69.4	97.2	$22,176	$0.9	$1.5	$2.2
Critical Cases	4.2	7.0	9.8	$1,814,400	$7.6	$12.7	$17.7
Total Value of Risk Reductions					$68.2	$113.7	$159.2

Valuing Time Savings for Head Start Families from Reductions in Absenteeism

We also anticipate reductions in time spent by parents or other caretakers providing needed support for children due to COVID-19 infections among Head Start staff. Several assumptions are necessary to quantify this impact. Since 273,000 Head Start staff provide services for 864,289 children, a 1:3.2 ratio, we assume that each staff missing work due to a COVID-19 infection means that an average of 3.2 children will need support from parents or other caretakers during this absence. We assume that a typical COVID-19 case results in two weeks of missed work, which corresponds to an average of 5 days a week, with 6 hours per day of providing Head Start services. Combining these assumptions, we estimate that cases of COVID-19 among Head Start staff results in an average of 190 hours of support for children that will be provided by a parent or other caretaker. *As discussed earlier, the interim final rule is anticipated to reduce COVID-19 cases among Head Start staff by a cumulative 510 to 1,198 cases over the time horizon of the analysis.*

Each of these cases averted corresponds to 190 hours of time saved by parents or other caregivers.

We also anticipate that a COVID-19 case at a center operating fully in-person can result in missed work for other Head Start staff who were in close contact and potentially exposed. This impact is limited to unvaccinated staff, since CDC guidance indicates that "[p]eople who are fully vaccinated do not need to quarantine if they come into close contact with someone diagnosed with COVID-19."[125] *We assume that all unvaccinated staff will be considered close contacts and need to quarantine. For simplicity, we adopt 20.2% as the share of Head Start staff unvaccinated on the last day of our baseline projections. We anticipate that Head Start staff at fully in-person centers represent 37% of the total staff cases, which is in line with the share of centers that are operating fully in-person, and that each center has about 13 staff, which is in line with the average number of staff per center. Among these 13 staff, about 3 are unvaccinated. To avoid double counting, we reduce this estimate by 1 to account for the initial COVID-19 case.*

To monetize these impacts, we adopt a value of time based on after-tax wages. Our approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices."[126] *We start*

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[125] https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-contact-tracing/about-quarantine.html

[126] https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.

with a measurement of the usual weekly earnings of wage and salary workers of $990.[127] *We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of $24.75. We adjust this hourly rate downwards by an effective tax rate of about 17%, resulting in a post-tax hourly wage rate of $20.55. We report a range for the total value of time saved of between $3.3 million and $7.5 million, depending on the vaccine coverage scenario.*

Table 6. Value of Time Savings from Reduced Absenteeism

Impact	**Low**	**Primary**	**High**
Cases Averted	510	854	1,198
Cases Averted at In-Person Centers	188	314	441
Unvaccinated Close Contacts	1.7	1.7	1.7
Additional Quarantines Averted	312	522	732
Total Absences Averted	822	1,376	1,930
Hours Saved Per Absentee	190	190	190
Total Hours Saved	156,198	261,406	366,614
Value of Time in Hours	$20.55	$20.55	$20.55
Value of Reduced Absenteeism	$3,210,121	$5,372,304	$7,534,486

As a sensitivity analysis, we augmented the post-tax wage rate to account for non-wage benefits. To capture non-wage benefits, we apply an estimate of the share of compensation from employer supplements to wages and salaries of about 18%, or $4.55 per hour using a pre-tax hourly wage as the base.[128] This results in a value of time of

[127] https://www.bls.gov/news.release/pdf/wkyeng.pdf*, second quarter of 2021.*

[128] https://fredblog.stlouisfed.org/2018/10/employer-contributions/.

$25.10 per hour. Using this alternative value of time, the value of time savings from reduced absenteeism would range from $3.9 million to $9.2 million, with a primary estimate of $6.6 million.

Benefits Related to Head Start Program Operating Status

We consider it probable that the substantial reduction in COVID-19 cases per day among Head Start staff and volunteers will result in fewer center closures due to COVID-19. For a number of reasons, the interim final rule will not eliminate the risk of COVID-19 among Head Start staff, volunteers, and children. Among these reasons, we do not expect that all staff and volunteers will be fully vaccinated under the interim final rule. We also do not expect many children to be fully vaccinated under either the baseline or any of the vaccine coverage scenarios under the policy for the time horizon of the analysis. As described in our discussion of the baseline scenario, being fully vaccinated is associated with a substantial reduction in the risk of a COVID-19 infection; however, it does not eliminate this risk. Thus, since the interim final rule will not eliminate the risk of COVID-19, we cannot reasonably conclude that all currently closed Head Start centers will reopen and remain open for the time horizon of the analysis. We do not estimate the reduction in closures anticipated due to the interim final rule; however, we present a calculation of how we would value this impact on a per-center basis.

As discussed in the Baseline section, the most recent data available at the time of this analysis indicates that 393 Head Start centers were closed due to COVID-19, representing about 2% of centers. We also presented an estimate of 17,264 children potentially unable to access Head Start services due to these closures, which is about 42 children per center. We restate the assumption that each child not served by these centers

requires 30 hours of support per week from family and caregivers that would normally be provided by Head Start staff and volunteers. This means each center closure results in 1,318 hours of support needed per week that would typically be provided by Head Start staff. Combined with the approach to valuing time described earlier, this means each center closure averted by the interim final rule could result in time saved for parents and caregivers valued at $25,722 per week. If 1% of total Head Start centers reopen as a result of the interim final rule, we would monetize these benefits at $5.3 million per week.

We also anticipate that the reduction in COVID-19 infection risks among Head Start staff, paired with the mask requirement, will result in a larger share of centers operating fully in person. As discussed in the Baseline section, 3,013 centers are operating in a virtual/remote status and 9,667 centers are operating in a hybrid status. We estimate that 125,679 children are receiving services in centers operating in a virtual/remote status and that 403,305 children are receiving services in centers operating in a hybrid status. We anticipate that centers transitioning from virtual/remote status to hybrid status, or from hybrid status to fully in-person status could result in time saved for parents and caregivers. We do not provide an estimate, but we expect the value of time saved for these impacts would be less than the value of time saved from reopening closed centers.

The value of time saved for families due to Head Start centers reopening, centers transitioning from virtual/remote status to hybrid status, and centers transitioning from hybrid status to fully in-person status are likely to be substantial. However, these time savings are only part of the anticipated benefits to children and families as the result of fewer closures, and more in-person services. Head Start *promotes school readiness for children in low-income families by offering educational, nutritional, health, social, and other services. We expect that Head Start centers that are able to reopen or move*

towards more in-person services under the interim final rule will be more effective in meeting these goals and the needs of Head Start families.

Valuing Health Benefits Among Head Start Volunteers

The interim final rule requires volunteers that interact with children at Head Start programs to be fully vaccinated. In 2019, approximately 1,061,000 adults volunteered in their local Head Start program. Of these, 749,000 were parents of Head Start children.[129] We have less information about these adults than for Head Start staff. For the purposes of providing estimates under the baseline and interim final rule, we make the following assumptions:

1. The baseline vaccine coverage rate for Head Start volunteers matches the overall adult vaccine coverage rate.
2. The mortality and morbidity risks for adult Head Start volunteers match the risks for Head Start staff, except through differences in vaccine coverage.
3. The requirement under the interim final rule will be less salient to unvaccinated volunteers than for staff since it is not linked to employment. We start with the lower-bound incremental vaccine-uptake estimate that, among unvaccinated adults, approximately 33.4% will be induced to get fully vaccinated. As discussed earlier, this estimate is based on an analysis of the Household Pulse Survey. We reduce this estimate by half, which is similar to excluding adults who are "unsure about getting a vaccine," and results in an incremental vaccine-uptake estimate of about 16.7%.
4. The volunteers most likely to be impacted by the policy are the volunteers associated with centers operating under a hybrid or fully in-person status. For volunteers at centers that are closed or in a virtual/remote operating status, we adopt an incremental vaccine-uptake of 0%.
5. We assume that the requirement will be even less salient for volunteers associated with centers operating in hybrid status. For these volunteers, we further reduce the incremental vaccine-uptake estimate by half, which is similar to excluding adults who "will probably get a vaccine." This results in an incremental-vaccine uptake of about 8.4%.
6. We do not estimate a second incremental vaccine-uptake scenario, such as the upper-bound full-compliance scenario for staff, since volunteers can comply with the requirement by choosing to not interact with children in an in-person Head Start setting. We also note that some of these volunteers may be induced to get vaccinated due to another COVID-19 vaccination requirement.

[129] https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/no-search/hs-program-fact-sheet-2019.pdf.

7. For the purposes of this analysis, we assume that volunteers are distributed evenly across Head Start centers, regardless of operating status.

Table 7 summarizes these assumptions for the number of volunteers, and the incremental vaccine-uptake assumptions that vary by center operating status.

Table 7. Vaccine Uptake Among Head Start Volunteers by Center Status

Center Status	Centers	Volunteers	Vaccine-Uptake Assumption
Closed	414	21,193	0.0%
Virtual/Remote	3,013	154,283	0.0%
Hybrid	9,667	495,097	8.4%
Fully In-Person	7,623	390,426	16.7%
Total	20,717	1,061,000	N/A

We follow identical steps for estimating the baseline scenario and policy scenario for Head Start staff, except to substitute the number of volunteers and vaccine-uptake assumptions for each center operating status category. As noted above, we also assume that the baseline vaccination coverage among volunteers matches the adult vaccination coverage, rather than the higher Head Start staff vaccination coverage.

Table 8 summarizes several measurable improvements in COVID-19 outcomes for Head Start volunteers at centers operating fully-in person that we attribute to the interim final rule. We estimate a total increase of 28,163 volunteers who are fully vaccinated, or about 2.7% of the total volunteers. To put this into the context of other vaccine requirements and to continue the discussion of attribution of impacts, we consider the Head Start volunteers under the baseline scenario who are also covered by the DOL ETS as employees of covered employers. DOL recently estimated 27.0% of covered employees would be vaccinated under the ETS, not including the 62.4% of covered employees

vaccinated in the baseline, pre-ETS.[130] If every Head Start volunteer was covered by this interim final rule, the DOL ETS as an employee of a covered employer, and no other vaccine requirements, our 2.6% estimate would attribute about 10% of the incremental vaccine coverage to this interim final rule and about 90% to the DOL ETS. As a sensitivity analysis on the appropriate attribution of impacts, we also report the net benefits of the interim final rule, excluding all benefits and costs associated with volunteers. These estimates are identical to the policy alternative of not including volunteers in the scope of the policy, which appears in Table 26.

For the baseline scenario of no new regulatory action, and for interim final rule scenario, we report the share of these volunteers that are fully vaccinated by March 1, 2022, and the corresponding cumulative cases, deaths, and hospital admissions averted over the time horizon of the analysis. Table 9 presents the same estimates for Head Start volunteers associated with centers in hybrid operating status. Table 10 presents the same estimates that combine Head Start volunteers associated with centers in virtual/remote and closed operating statuses. Table 11 presents the estimates for all Head Start volunteers.

[130] https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23643.pdf. Table IV.B.8.

Table 8. Impacts Among Volunteers at In-Person Centers

Outcome	Baseline	Interim Final Rule	Difference
Fully Vaccinated Rate	73.8%	78.2%	4.4%
Cumulative Cases	10,368	10,035	-333
Cumulative Deaths	130.1	122.9	-7.2
Cumulative Hospital Admissions			
Non-ICU	731	693	-37
ICU	158	150	-8
Total	888	843	-45

Table 9. Impacts Among Volunteers at Hybrid Centers

Outcome	Baseline	Interim Final Rule	Difference
Fully Vaccinated Rate	73.8%	76.0%	2.2%
Cumulative Cases	13,421	13,273	-148
Cumulative Deaths	170.6	167.2	-3.4
Cumulative Hospital Admissions			
Non-ICU	957	940	-17
ICU	206	203	-4
Total	1,163	1,142	-21

Table 10. Impacts Among Volunteers at Virtual/Remote and Closed Centers

Outcome	Baseline	Interim Final Rule	Difference
Fully Vaccinated Rate	73.8%	73.8%	0.0%
Cumulative Cases	5,599	5,599	0
Cumulative Deaths	71.9	71.9	0
Cumulative Hospital Admissions			
Non-ICU	400	400	0

ICU	86	86	0
Total	486	486	0

Table 11. Impacts Among All Head Start Volunteers

Outcome	**Baseline**	**Interim Final Rule**	**Difference**
Cumulative Cases	29,388	28,907	-481
Cumulative Deaths	372.6	362.1	-10.6
Cumulative Hospital Admissions			
Non-ICU	2,087	2,033	-55
ICU	450	438	-12
Total	2,538	2,471	-66

We value the mortality and morbidity risk reductions experienced by Head Start volunteers following an identical methodology described above for Head Start staff. This includes the process for categorizing morbidity reductions by case-severity category, and the adjustments to prevent double counting. Table 12 presents the total value of COVID-19 mortality and morbidity risk reductions for Head Start volunteers across all centers, for a 3% discount rate, *which affects the value per quality-adjusted life year estimates underlying the VSC estimates. Table 13 presents the same estimates for a 7% discount rate.*

Table 12. Value of COVID-19 Risk Reductions Among Volunteers, 3% Discount Rate

Risk Reduction	**Impact**	**VSL or VSC (3%)**	**Value of Risk Reduction**
Mortality Reductions	10.6	$11,501,365	$121,440,804
Morbidity Reductions			
Mild Cases	414	$5,846	$2,422,527

Severe Cases)	54.5	$13,104	$714,294
Critical Cases	1.2	$1,814,400	$2,176,442
Total Value of Risk Reductions			$126,754,066

Table 13. Value of COVID-19 Risk Reductions Among Volunteers, 7% Discount Rate

Risk Reduction	**Impact**	**VSL or VSC (7%)**	**Value of Risk Reduction**
Mortality Reductions	10.6	$11,501,365	$121,440,804
Morbidity Reductions			
Mild Cases	414	$9,778	$4,051,467
Severe Cases	54.5	$22,176	$1,208,805
Critical Cases	1.2	$1,814,400	$2,176,442
Total Value of Risk Reductions			$128,877,518

Summary of Monetized Benefits

We identify several sources of monetized benefits that are attributable to the interim final rule. Table 14 reports the monetized benefits from mortality and morbidity risk reductions to Head Start staff, mortality and morbidity risk reductions to Head Start volunteers, and time savings for parents and caregivers. These estimates cover both Head Start staff vaccination coverage scenarios, and correspond to VSC estimates using a 3% discount rate. All estimates cover the time period between the publication of the interim final rule and March 1, 2022, and are reported in 2020 dollars. Table 15 reports the same estimates using a 7% discount rate.

Table 14. Monetized Benefits Attributable to the Interim Final Rule, 3% Discount Rate

Value of Impact	**Low**	**Primary**	**High**

COVID-19 Risk Reductions, Staff	$66,021,974	$110,059,221	$154,096,444
COVID-19 Risk Reductions, Volunteers	$126,754,066	$126,754,066	$126,754,066
Absenteeism Reductions	$3,210,121	$5,372,304	$7,534,486
Total Monetized Benefits	$195,986,161	$242,185,591	$288,384,996

Table 15. Monetized Benefits Attributable to the Interim Final Rule, 7% Discount Rate

Value of Impact	**Low**	**Primary**	**High**
COVID-19 Risk Reductions, Staff	$68,206,983	$113,715,169	$159,223,331
COVID-19 Risk Reductions, Volunteers	$128,877,518	$128,877,518	$128,877,518
Absenteeism Reductions	$3,210,121	$5,372,304	$7,534,486
Total Monetized Benefits	$200,294,622	$247,964,991	$295,635,335

In addition to the impacts that we monetize in this analysis, we anticipate that the increase in vaccine coverage attributable to the interim final rule will result in indirect health benefits from reduced transmission of SARS-COV-2. These impacts include reductions in secondary infections from vaccinated Head Start staff and volunteers to other staff and volunteers, children, and families. We anticipate that the masking requirement will also reduce transmission at in-person Head Start settings from individuals covered by the requirement. This impact includes a reduction in COVID-19 transmission from children to Head Start teachers, staff, and other children. The reductions in transmission attributable to the interim final rule will result in additional, unquantified reductions in mortality and morbidity risks to Head Start children and families, and to the general public.

We request comment on potential quantitative estimation of benefits for Head Start staff who receive exemptions (associated with ancillary provisions and reduced exposure when colleagues are vaccinated) using a study by Chen, Glymour, et al. (2021).[131] In this paper,

[131] Chen, Yea-Hung, Maria Glymour, Alicia Riley, John Balmes, Kate Duchowny, Robert Harrison, Ellicott Matthay, Kirsten Bibbins-Domingo. “Excess mortality associated with the COVID-19 pandemic among

estimates of excess mortality among 18- to 65-year-olds in California during the eight months from March to October, 2020, are summarized across various industry categories, including teacher assistants, for whom the estimated ratio is 1.28.[132] The "unemployed or missing [employment data]" category has an excess mortality risk ratio of 1.23—which may yield a reasonable estimate of the new risk level in cases of rule-induced staff turnover. During most of the eight months covered by the Chen et al. study, California imposed stay-at-home requirements, but these policies were relaxed somewhat during the early and mid-summer, the result being an increase in COVID-19 mortality. Visual inspection of Chen et al.'s Figure 2 allows for estimation analogous to that described above, using the excess mortality risk ratios for August 1, and yielding a result that the scope for workplace safety improvements is lesser in the context of relatively free movement and activity, as compared with a situation of broader non-workplace mitigation measures. In other words, whatever the overall effectiveness of Cal/OSHA's workplace health and safety requirements—presumably similar to this IFR's ancillary provisions—it should be reduced substantially when extrapolated to a context without widespread stay-at-home policies. An additional tendency toward overstatement in the potential estimation approach exists because it does not incorporate a netting off of the impacts of other jurisdictions'—including California's own—mitigation activities. (In

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Californians 18–65 years of age, by occupational sector and occupation: March through October 2020." medRxiv 2021.01.21.21250266; doi: https://doi.org/10.1101/2021.01.21.21250266.

[132] The list of occupations with specific estimates differs, omitting teacher assistants, in a subsequent version of the paper. Chen, Yea-Hung, Maria Glymour, Alicia Riley, John Balmes, Kate Duchowny, Robert Harrison, Ellicott Matthay, Kirsten Bibbins-Domingo. "Excess mortality associated with the COVID-19 pandemic among Californians 18–65 years of age, by occupational sector and occupation: March through November 2020." *PLoS One*, June 4, 2021 https://doi.org/10.1371/journal.pone.0252454.

other words, it would be necessary to use the correct baseline before attributing benefits to this IFR.) By contrast, this suggested quantification method has a tendency toward underestimation in that it does not account for reduction in exposure due to exemption-receiving Head Start staff being surrounded by colleagues who are more widely vaccinated. In addition to seeking comment on how to address these challenges in a potential quantitative estimate of benefits for exemption recipients, we request feedback on the potential to use literature such as Chen, Glymour et al. to proxy the new risk level for non-turnover cases.

F. Costs of the Rule

The most significant cost of the interim final rule stems from the potential for Head Start staff to decline COVID-19 vaccination. This would result in a number of potential consequences, each of which is likely to represent a substantial social cost. Table 16 presents the number of Head Start staff anticipated to be fully vaccinated under the vaccine coverage scenarios, under a shared assumption that 5% of Head Start staff will seek and receive an exemption from the vaccination requirement. Under the lower-bound vaccine coverage scenario, as many as 23,035 Head Start staff will not meet the vaccination requirement and also not receive an exemption. The upper-bound vaccine coverage scenario reflects all Head Start staff that do not meet the vaccination requirement receiving an exemption. Under our primary scenario, 11,517 Head Start Staff will not meet the vaccination requirement and also not receive an exemption from the vaccination requirement.

Table 16. Head Start Staff COVID-19 Vaccine Requirement Response Possibilities

Outcome Under Policy Scenario	**Low**	**Primary**	**High**

Fully Vaccinated Rate	86.6%	90.8%	95.0%
Exemption Rate	5.0%	5.0%	5.0%
Compliance Rate, Pre-Turnover	91.6%	95.8%	100.0%
Head Start Staff in Compliance, Pre-Turnover	249,965	261,483	273,000
Potential Head Start Staff Turnover	23,035	11,517	0

We anticipate some staff employed by Head Start programs will choose to leave the program due to vaccination and mask mandates. There are already significant challenges in recruiting and retaining staff among early care and education providers including Head Start and the requirements in this rule could exacerbate this issue for certain programs, resulting in programs not being able to fully staff their classrooms. This could also result in costs to programs to recruit new qualified staff to replace those staff that leave the program and may result in interruption of services for children and families.

Costs Associated with Head Start Staff Vacancies

In this section, we describe our approach for valuing the costs associated with Head Start staff vacancies associated with quitters that are attributable to the interim final rule. We follow many of the assumptions contained in the Benefits section that outline the value of time savings for parents and caretakers of children attributable to the interim final rule through vaccine coverage and reduced COVID-19 cases among Head Start teachers. For each COVID-19 case averted, parents and caretakers experienced 190 hours of time savings, assuming each COVID-19 case lasts two weeks. To value the countervailing risk of staff vacancies, we adopt an assumption that each Head Start staff that quits in response to the interim final rule will leave a vacancy that lasts an average of two weeks. This assumption is intended to reflect an average duration among vacancies that are filled faster and vacancies that are filled slower than two weeks. It is also intended to be inclusive of any efforts by Head Start centers that anticipate resignations on the effective date of the policy to identify replacements when the vaccine requirement takes effect. We also anticipate that Head Start centers will be able to prepare in advance for these vacancies and reduce the impact on families through increased caseloads per staff. This preparation would not be possible for absenteeism due to a COVID-19 case or outbreak. We reduce the average number of families affected by half, which results in an overall estimate of about 95 hours of time costs for parents and caretakers of children receiving Head Start services per vacancy from resignations. We are not aware of another estimate of how long a typical vacancy of this nature lasts; however, given that we anticipate this to be a significant cost attributable to the interim final rule, we have determined that these assumptions are more justified, in the context of this analysis, than not monetizing this cost. We acknowledge significant uncertainty in several of these estimates and discuss the nature of and implications of each source.

We also include a cost of training the replacement Head Start staff. We assume that new-employee training takes an average of 40 hours, and we adopt a value of time based on the median wage rage of preschool and kindergarten teachers of $14.36 per hour[133]. We double this wage to generate a fully loaded wage that accounts for benefits and other indirect costs. Table 17 reports the costs of vacancies and costs of training under the vaccine coverage scenarios.

[133] https://www.bls.gov/oes/current/naics4_624400.htm

Table 17. Costs of Staff Vacancies

Impact	Low	Primary	High
Vacancies	23,035	11,517	0
Hours per Vacancy	95	95	95
Total Hours	2,187,747	1,093,873	0
Value of Time	$20.55	$20.55	$20.55
Subtotal, Vacancy Costs	$44,961,638	$22,480,819	$0
Hours Training			
Replacements	40	40	40
Value of Time	$28.72	$28.72	$28.72
Subtotal, Training Costs	$26,462,078	$13,231,039	$0
Total	$71,423,717	$35,711,858	$0

Table 17 presents cost estimates that vary by the vaccine coverage scenarios, which directly impact the number of vacancies that we attribute to the interim final rule. For these calculations, we adopt a common estimate of two weeks for Head Start centers to fill these vacancies. As noted in the baseline section, early care and education providers are currently experiencing significant challenges in recruiting and retaining staff that are attributable to the COVID-19 pandemic and general trends in early care and education labor markets. The general trends in early care and education labor markets suggest that filling these vacancies could take longer than two weeks. However, the interim final rule directly addresses the risk of SARS-COV-2 transmission at Head Start centers. The vaccination and masking requirements might lead to new hiring of employees who would not feel safe working in these environments absent these rules. This effect would reduce the average time to fill each vacancy. Alternatively, this could represent an additional source of benefits not captured in the main analysis elsewhere.

These cost estimates reflect one approach to account for the cost of staff vacancies. Other approaches may be reasonable. For example, in the context of its interim final rule with comment period that requires COVID-19 vaccinations for workers in most health care settings that receive Medicare and Medicaid reimbursement, CMS calculates the likely magnitude of hiring costs by applying an analysis of the direct hiring costs for workers in the long-term care sector.[134] After updating for inflation, CMS reports a direct hiring cost of $4,000 per worker.[135] The total cost estimates in Table 17 amount to $3,100 per worker. Substituting CMS's per-worker estimate would result in a range of total cost estimates from $0 to $92 million, with a central estimate of $46 million.

The cost of staff vacancies estimates also reflect an estimate of the value of time of $20.55 per hour, which we also use to estimate the benefits from reduced absenteeism. In a sensitivity analysis for those benefits, we applied a higher value of time of $25.10. Performing an identical sensitivity analysis for these costs yield a higher central estimate of vacancy costs of $27.5 million, which is a $5.0 million increase compared to the estimate in Table 17. This value of time would also yield a higher estimate of vacancy costs under the low-coverage scenario of $54.9 million, which is a $10.0 million increase compared to the estimate in Table 17.

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[134] Dorie Seavey, "The Cost of Frontline Turnover in Long-Term Care," Better Jobs Better Care Report, Washington, DC: Institute for the Future of Aging Services, American Association of Homes and Services for the Aging. 2004

[135] https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23831.pdf.

In addition to the costs we identify and monetize related to staff vacancies, we also note the potential costs associated with reduced support from volunteers. However, as with staff, it is also conceivable that some individuals who do not currently feel safe volunteering at in-person Head Start settings will feel comfortable volunteering under the interim final rule. On net, this could increase the support Head Start centers receive from volunteers.

Cost to Head Start Staff and Volunteers to Get Fully Vaccinated

We identify a second cost related to Head Start staff and volunteers getting fully vaccinated. We adopt an estimate of 2 hours as the time necessary to receive one COVID-19 vaccine dose, and adopt a simplifying assumption that each individual induced to get fully vaccinated under the interim final rule will receive two vaccine doses. This estimate is intended to be inclusive of scheduling time; commuting time; time receiving a vaccine dose; waiting time, including after receiving a vaccine dose to watch for any reactions; and recovery time. We value the time spent to get fully vaccinated using a $20.55 per hour value of time, described above, for a total value of time per person of about $82. We also include costs associated with the vaccine doses and costs of administration. Using an estimated $20 cost per dose of vaccine, $20 as the cost per vaccine administration, we compute the cost of vaccine doses and administration of $80 per person. Table 18 reports the total costs related to vaccination.

Table 18. Costs Related to Vaccination

Cost Element	**Low**	**Primary**	**High**
Additional Staff Vaccinated	18,436	29,953	41,470
Additional Volunteers Vaccinated	28,163	28,163	28,163

Hours to Receive One Dose	2	2	2
Doses per Person	2	2	2
Value of Time in Hours	$20.55	$20.55	$20.55
Value of Time per Person	$82	$82	$82
Subtotal, Value of Time for Staff	$1,515,532	$2,462,324	$3,409,116
Subtotal, Value of Time for Volunteers	$2,315,203	$2,315,203	$2,315,203
Cost per Dose of Vaccine	$20	$20	$20
Cost per Vaccine Administration	$20	$20	$20
Doses per Person	2	2	2
Cost of Vaccine Doses and Administration per Person	$80	$80	$80
Subtotal, Vaccine Doses and Administration	$3,727,923	$4,649,305	$5,570,686
Total Costs of Vaccination	$7,558,658	$9,426,831	$11,295,005

The costs related to vaccination reflect an estimate of the value of time, $20.55 per hour, used elsewhere in this analysis. In other cases where this value of time is applied, we have also performed a sensitivity analysis that applies a higher value of time of $25.10. Performing an identical sensitivity analysis for these costs yields a value of time per person to get vaccinated of about $100. This higher value of time results in total costs of between $8.4 million and $12.6 million, with a central estimate of $10.5 million, which is an increase of between $0.8 million and $1.3 million. Regardless of the chosen value of time, the costs in Table 18 may be underestimated, since they do not include costs associated with adverse events reported after COVID-19 vaccination.[136]

Cost of Masking

[136] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

This regulation also requires mask wearing for all adults and children age 2 and older in certain in-person Head Start settings. As an intermediate step, we estimate the total in-person days per week for staff, children, and volunteers. We replicate the in-person days per week for staff and children using the estimates reported in Table 3, but we reduce the estimate for children by 14% to account for children younger than age 2 that are not subject to the requirement. To estimate the in-person days per week for volunteers, we assume they are evenly distributed across center by operating status, such that 390,426 are associated with fully in-person centers, and 495,0975 are associated with centers in hybrid operating status. For purposes of this calculation, we assume that volunteers associated with in-person centers will volunteer in person an average of once per week, and that volunteers at centers in hybrid operating status will volunteer in person an average of once every other week. We expect that the 175,476 combined volunteers associated with closed or virtual/remote centers will not volunteer in-person. These assumptions and data indicate that Head Start volunteers will average 637,975 in-person days per week.

We assume that each staff, child, and volunteer will use one mask per day, and adopt an estimate of the cost per surgical mask of $0.14.[137] We anticipate that staff, children, and volunteers will combine for a total of 3,693,426 masks per week, with the total weekly cost of these masks of $517,080. We anticipate that a substantial portion of these individuals would wear masks when in-person at Head Start programs without this requirement, and adopt an estimate of 25% for the share of these costs that are attributable to the interim final rule. Finally, we calculate that the masking requirement

[137] https://www.regulations.gov/document/OSHA-2020-0004-1033, Table VI.B.14.

will be effective for the entire time horizon of this analysis. Table 19 reports the costs of masking that are attributable to the interim final rule.

Table 19. Costs of Masking Attributable to the Interim Final Rule

Cost Element	Estimate
In-Person Days per Week, Staff	820,769
In-Person Days per Week, Children	2,598,467
In Person Days per Week, Children (2+)	2,234,682
In Person Days per Week, Volunteers	637,975
Masks per Person per Day	1
Total Masks per Week	3,693,426
Cost per Mask	$0.14
Total Cost of Masks per Week	$517,080
Attributable Share	25%
Weekly Attributable Costs	$129,270
Weeks Effective	13
Total Masking Costs	$1,680,509

Cost of Testing

We also identified a cost of testing Head Start staff and volunteers that receive an exemption from the vaccine requirement. Across all scenarios, we anticipate that 5% of Head Start Staff will receive an exemption, so 13,650 staff will be unvaccinated under the interim final rule. We further assume that 5% of Head Start volunteers, or about 53,050, will also receive an exemption. We assume that only staff and volunteers associated with Head Start centers that are fully in-person or in hybrid status will be tested. We assume that Head Start staff and volunteers will be tested weekly, and that this requirement will be effective for about 4 weeks of the time horizon of the analysis, from January 31, to March 1, 2022. This effective period is shorter than for the masking provision, which is effective immediately. We calculate that about 230,627 tests will be performed, and

adopt an estimate of $10 per test. Table 20 presents these estimates and the total cost estimate of about $2.3 million. For the purpose of this analysis, we assume that the costs of testing are borne by the Head Start centers.

Table 20. Cost of Testing Unvaccinated Staff

Cost Element	**Estimate**
Exempted Staff	13,650
Exempted Volunteers	53,050
Total Exemptions	66,700
Share of Exemptions at In-Person/Hybrid Centers	83%
Head Start Staff and Volunteers Requiring Testing	55,669
Tests Per Week	1
Weeks Effective	4
Total Tests	230,627
Cost Per Test	$10
Total Cost of Testing	$2,306,273

Recordkeeping Costs

We anticipate that the interim final rule will result in recordkeeping activities. The Paperwork Reduction Act analysis estimates the total burden of 6,670 hours. To monetize this impact, we apply an estimate of the hourly wage of Education and Childcare Administrators, Preschool and Daycare, for individuals working in the Child Day Care Services industry. According to the U.S. Bureau of Labor Statistics, the hourly mean

wage for these individuals is $24.78 per hour.[138] We adjust this hourly rate to account for benefits and other indirect costs by multiplying by two, for a fully loaded hourly wage rate of $49.56. Multiplying the fully loaded wage rate by the number of hours results in a total cost of $330,565.20.

Total Costs

We identify several sources of costs that are attributable to the interim final rule. Table 21 reports the monetized costs related to staff vacancies, costs of vaccination, costs of masking, costs of testing, and costs of recordkeeping. These estimates cover the Head Start staff vaccination coverage scenarios, and do not differ by discount rate. All estimates cover the same time horizon and are reported in 2020 dollars.

Table 21. Monetized Costs Attributable to the Interim Final Rule

Value of Impact	**Low**	**Primary**	**High**
Staff Vacancies	$44,961,638	$22,480,819	$0
Training	$26,462,078	$13,231,039	$0
Vaccination	$7,558,658	$9,426,831	$11,295,005
Masking	$1,680,509	$1,680,509	$1,680,509
Testing	$2,306,273	$2,306,273	$2,306,273
Recordkeeping	$330,565	$330,565	$330,565
Total Monetized Costs	$83,299,721	$49,456,037	$15,612,352

[138] https://www.bls.gov/oes/current/oes119031.htm. Wage rage for job code 11-9031.

We consider it probable that the substantial reduction in COVID-19 cases per day among Head Start staff will result in fewer center closures due to COVID-19. We do not estimate the reduction in closures anticipated due to the interim final rule; however, we presented a calculation of how we would value the benefit of reopening on a per-center basis. For comparison, we also estimate the additional cost of masking, and additional cost of testing exempted staff and volunteers for centers that reopen.

If 1% of total Head Start centers reopen as a result of the interim final rule, this would result in 207 centers reopening. For the purposes of this cost analysis, we calculate the number of masks required under for a center operating fully in-person. This would result in 2,730 staff, 8,643 children, 10,610 volunteers wearing masks at in-person Head Start settings. They would require 67,474 masks on a weekly basis, 16,869 of which we attribute to the interim final rule. The total cost of these additional masks would be $2,362 per week. For testing, the same number of centers reopening would result in 667 additional exempted staff and volunteers requiring testing every week, which corresponds to $6,670 in testing costs per week. These costs sum to $9,031 per week. To continue the comparison, if 1% of closed centers reopen, we would monetize the benefits in time saved for parents and caregivers at $5.3 million per week. This comparison only includes impacts we are able to monetize, and does not account for changes in COVID-19 risks associated with reopening. As discussed elsewhere, these risks will be reduced as a result of the vaccination and masking requirements.

G. Net Benefits

We have analyzed the major impacts of the interim final rule under several scenarios of incremental vaccine-uptake among Head Start staff that are unvaccinated in the baseline scenario of no new regulatory action. In previous sections, we have indicated that the

benefits are higher and that the costs are lower under the high vaccine coverage scenario than the low vaccine coverage scenario. In this section, we demonstrate the magnitudes. Table 22 presents the total costs, benefits, and net benefits that are attributable to the interim final rule under a 3% discount rate. Table 23 presents these same estimates using a 7% discount rate. Both sets of estimates cover the same time horizon.

Table 22. Net Benefits, 3% Discount Rate, 2020 dollars

Total Impacts	**Low**	**Primary**	**High**
Benefits	$195,986,161	$242,185,591	$288,384,996
Costs	$83,299,721	$49,456,037	$15,612,352
Net Benefits	$112,686,440	$192,729,554	$272,772,644

Table 23. Net Benefits, 7% Discount Rate, 2020 dollars

Total Impacts	**Low**	**Primary**	**High**
Benefits	$200,294,622	$247,964,991	$295,635,335
Costs	$83,299,721	$49,456,037	$15,612,352
Net Benefits	$116,994,900	$198,508,954	$280,022,983

An analytic issue not addressed in the assessment underlying these results is the question of how to interpret individuals' hesitation or unwillingness, in the absence of regulation, to accept an intervention that achieves extensive health protection for themselves, with little or no out-of-pocket cost, and ever-lessening time or inconvenience cost; a simplistic revealed-preference monetization of the rule's effect would be that it yields minimal or negative benefits for such staff members, even the ones for whom it prevents or reduces severity of COVID-19 infection. Given the dynamic nature of the pandemic—including scientific innovations and other human responses—it may be that long-run equilibrium for COVID-19 vaccines has not been reached, in which case the above use of VSL-

related estimates for staff-member risk valuation may be appropriate at this time. On the other hand, other valuation approaches may also be worth exploring.

Toward that end, we use Herzog and Schlottmann (1990) to estimate a cap on how much the benefits of an employment-based health or safety regulation could exceed its costs.[139] *Under this model, benefits accrue partially to workers in the form of health and longevity improvements (net of lost wage premiums) and partially to employers in the form of wage reductions, and the sum of worker and employer portions equals the monetized value of health and longevity improvements. Herzog and Schlottmann find that the wage reduction portion of total benefits is somewhere between 42.9% (=$4.29/$10.01) and 74.3% (=$3.67/$4.94). Put another way, the total benefits of a rule should be no more than 1.3 (=$4.94/$3.67) to 2.3 (=$10.01/$4.29) times the regulatory costs incurred by employers; otherwise, the wage reductions experienced by those employers would make it profit-maximizing (or surplus-maximizing, for non-profit entities) for them to mandate vaccination or perform the other risk-abatement activities without a regulation forcing them to do so.*

The first several rows of Table 24 show upper bounds on staff benefits estimated by applying the Herzog and Schlottmann ratios to the estimated costs of the IFR (assuming

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[139] Herzog, Henry W. and Alan M. Schlottmann. *"Valuing Risk in the Workplace: Market Price, Willingness to Pay, and the Optimal Provision of Safety," The Review of Economics and Statistics 72(3): August 1990, pp. 463-470.*

for simplicity, as elsewhere in this analysis, that employers incur the costs).[140] *Unlike in Tables 22 and 23, and the analysis that feeds into them, the quantified staff benefits in Table 24 are not necessarily limited to individuals who are newly vaccinated. Another, even more fundamental difference, is that Table 24 demonstrates an approach in which low costs are correlated with low staff benefits and high costs with high staff benefits.*

Table 24. Net Benefits Upper Bounds, Alternative Approach, 2020 dollars

Total Impacts *	**Low**	**Middle**	**High**
Costs	$15,612,352	$49,456,037	$83,299,721
Upper Bound Staff Benefits, Using 1.3 Ratio	$21,014,991	$66,570,251	$112,125,510
Upper Bound Staff Benefits, Using 2.3 Ratio	$36,428,821	$115,397,419	$194,366,016
Upper Bound Total Benefits, Using 1.3 Ratio	$157,426,995	$200,820,072	$244,213,149
Upper Bound Total Benefits, Using 2.3 Ratio	$172,840,824	$249,647,240	$326,453,655
Upper Bound Net Benefits, Using 1.3 Ratio	$141,814,643	$151,364,036	$160,913,428
Upper Bound Net Benefits, Using 2.3 Ratio	$157,228,473	$200,191,203	$243,153,934

* Non-staff benefits per Table 15.

[140] *Herzog and Schlottmann use an old data set (1965-1970) and focus on work settings quite different from child care centers. We request comment on whether more recent or better-tailored inputs are available.*

H. Distributional Effects

Executive Order 13985 on *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* includes consideration of agency policies and actions that create or exacerbate barriers to full and equal participation by all eligible individuals. As noted previously, a large share of children served by Head Start programs are from culturally and linguistically diverse families. And the majority of Head Start children are also from families experiencing poverty. In FY 2019, OHS administrative data indicate that 37% of Head Start children were Hispanic or Latino and the remaining 63% were of non-Hispanic or Latino origin. Further, 44% were White, 30% were Black or African American, 10% were biracial or multi-racial, 4% were American Indian or Alaska Native, and 2% were Asian.[141] As is evident with these data, the indirect beneficiaries of this IFR – the children and families served by Head Start programs – are disproportionately from diverse racial and ethnic groups, as well as from low-income families, and they will benefit greatly from reduced exposure to COVID-19 from teachers who are newly vaccinated.

I. Uncertainty and Sensitivity Analysis

In the main analysis, we report the value of COVID-19 mortality risk reductions using the central HHS estimate of the VSL of $11.5 million, and value of morbidity risk reductions using estimates of the VSC that are derived from the central VSL. As a sensitivity analysis, we recalculate these benefits using the low and high estimates of the

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[141] Source: Head Start Program Information Report; the remaining 10% of children were reported as "Other or Unspecified."

VSL, which range from $5.3 million to $17.5 million. Table 25 reports the value of these risk reductions using the full range of VSL estimates.

Table 25. Value of COVID-19 Risk Reductions Using Range of VSL Estimates, 3% Discount Rate

Risk Reduction	VSL or VSC Estimate			Value of Risk Reduction ($ millions)		
	Low	Central	High	Low	Central	High
Mortality Reductions	$5,367,303	$11,501,365	$17,507,633	$99.6	$213.4	$324.9
Morbidity Reductions						
Mild Cases	$2,728	$5,846	$8,900	$3.2	$6.9	$10.5
Severe Cases	$6,115	$13,104	$19,947	$0.8	$1.6	$2.5
Critical Cases	$846,720	$1,814,400	$2,761,920	$6.9	$14.8	$22.6
Total Value of Risk Reductions				$110.5	$236.8	$360.5

In our main analysis, we assume that the vaccination, masking, and other requirements will be in effect for the entire time horizon of the analysis. We also considered a scenario that these requirements will end at an earlier point in time. Specifically, we evaluated a scenario that the requirements would be repealed through subsequent rulemaking or expire on January 16, 2022, which corresponds to the last day of the most recent renewal of the COVID-19 public health emergency.[142] For this scenario, we assume that Head Start staff are surprised on January 16, 2022 by the announcement, and that unvaccinated staff discontinue efforts to get fully vaccinated. This results in a lower vaccine coverage rate of between 84.9% and 91.5%, compared to a vaccine coverage rate of between 86.6% and 95.0% under the scenario of the requirement in effect through at least January

[142] https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVDI-15Oct21.aspx

31, 2022. This would result in smaller reductions in mortality and morbidity risks, and smaller reductions in absenteeism. It would also eliminate the costs from staff vacancies and training attributable to the interim final rule, substantially reduce the costs of masking and testing; and reduce the total costs of vaccinations.

J. Analysis of Regulatory Alternatives to the Rule

We evaluated several regulatory alternatives to the interim final rule. First, we assessed the impact of not including volunteers in the scope of the vaccine requirement of the interim final rule. Under this regulatory alternative, the reductions in mortality and morbidity for volunteers induced to get fully vaccinated outlined in Tables 12 and 13 would not occur. We also anticipate a reduction in costs attributable to the rule related to the costs related to vaccination described in in Table 18. Table 26 reports the net benefits of this policy alternative, using a 3% discount rate. Compared to our analysis of the interim final rule, this option would result in lower net benefits under the vaccine coverage scenarios that we analyzed.

Table 26. Net Benefits of Policy Alternative, 3% Discount Rate, 2020 dollars

Total Impacts	**Low**	**Primary**	**High**
Benefits	$69,232,095	$115,431,524	$161,630,929
Costs	$78,731,453	$44,887,768	$11,044,084
Net Benefits	-$9,499,358	$70,543,756	$150,586,846

We also considered two alternatives to the masking requirement. One alternative includes eliminating the masking requirement entirely. This policy alternative would reduce the cost estimates of the interim final rule by $1.7 million in line with the calculations

presented in Table 19. A second alternative would limit the masking requirement to unvaccinated individuals. Under this policy alternative, the weekly masks needed for Head Start staff and volunteers would be reduced significantly, in line with the vaccine coverage rates. When the vaccination requirement takes effect, only the 5% of Head Start staff and volunteers who receive an exemption would be expected to wear a mask. This reduces the weekly masks for Staff and volunteers attributable to the rule by about 95%. This policy alternative would also result in small reduction in the number of masks needed for children. About 1% of Head Start children are age 5 years and older, and some of these children may get vaccinated in response to CDC's "recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine."[143] We estimate that the cost of masking under this policy alternative would be about $1.0 million, which is about $0.6 million lower than the masking requirement under the interim final rule.

While we do not include a monetized benefit for the masking requirement, we anticipate that it will reduce transmission of SARS-COV-2 at in-person Head Start settings from individuals covered by the requirement. This impact includes a reduction in transmission from children to Head Start teachers, staff, and other children. The reductions in transmission attributable to the interim final rule will result in additional, unquantified reductions in mortality and morbidity risks to Head Start children and families, and to the general public. Compared to the analysis of the interim final rule, the two masking policy alternatives would result in fewer averted COVID-19 cases, hospitalizations, and deaths.

[143] https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html.

Finally, we considered a policy alternative of linking the vaccination, masking, and other requirements of the interim final rule to the COVID-19 public health emergency. Evaluating this policy alternative requires an additional assumption about the duration of the public health emergency. In the Uncertainty and Sensitivity Analysis, we explore a scenario in which the requirements would be repealed through subsequent rulemaking or expire on January 16, 2022, which corresponds to the last day of the most recent renewal of the COVID-19 public health emergency. That sensitivity analysis represents one possible outcome for this policy alternative. The main analysis, which assumes that the requirements will remain in effect through the time horizon of this analysis, represents another possible outcome for this policy alternative.

III. Final Small Entity Analysis

We have examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act. This analysis, as well as other sections in this Regulatory Impact Analysis, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The U.S. Small Business Administration (SBA) maintains a Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS).[144] We replicate the SBA's description of this table:

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[144] U.S. Small Business Administration (2019). "Table of Size Standards." August 19, 2019. https://www.sba.gov/document/support--table-size-standards.

This table lists small business size standards matched to industries described in the North American Industry Classification System (NAICS), as modified by the Office of Management and Budget, effective January 1, 2017. The latest NAICS codes are referred to as NAICS 2017.

The size standards are for the most part expressed in either millions of dollars (those preceded by "$") or number of employees (those without the "$"). A size standard is the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm.

This interim final rule will impact small entities in NAICS category 624410, Child Day Care Services, which has a size standard of $8.0 million dollars. We assume that all 20,717 Head Start centers are below this threshold and are considered small entities.

B. Description of the Impacts of the Rule on Small Entities

We identify three categories of costs of the interim final rule that could impact small entities. Specifically, we expect that small entities will need to train Head Start staff to replace those who resign, and monetize these costs at about $13.2 million. For the purposes of this calculation, we assume that Head Start centers will purchase masks sufficient to cover every in-person staff, child, and volunteer, at a cost of about $1.7 million. We also assume that Head Start centers will incur the costs of testing for staff, at a cost of about $2.3 million. Finally, we attribute the costs of recordkeeping to small entities, at a cost of about $0.3 million. These combine for a total cost to small entities of $17.5 million. Dividing by the 20,717 Head Start centers, these costs are about $847 per

small entity. As an alternative calculation, we estimate these costs are $864 per small entity, excluding closed Head Start centers.

Table 27. Costs Per Small Entity

Impact	Costs to Small Entities	Cost Per Small Entity
Training	$13,231,039	$638.66
Masking	$1,680,509	$81.12
Testing	$2,306,273	$111.32
Recordkeeping	$330,565	$15.96
Total	$17,548,386	$847.05

The Department considers a rule to have a significant impact on a substantial number of small entities if it has at least a 3% impact on revenue on at least 5% of small entities. Therefore, we perform a threshold analysis to determine whether these costs are likely to result in a significant impact on a substantial number of small entities. For $847 to exceed the impact threshold, a small entity would need to have revenue below $28,235 over the time horizon of the analysis, or annual revenue of less than about $113,000.

The Administration for Children and Families awards about $10 billion in grants to Head Start programs, including Early Head Start-Child Care Partnerships.[145] Across 20,717 centers, this averages to $466,192, which is well above the $113,000 threshold. Thus, we conclude that the interim final rule is not likely to result in a significant impact on a substantial number of small entities.

[145] https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/no-search/hs-program-fact-sheet-2019.pdf

List of Subjects in 45 CFR Part 1302

COVID-19, Education of disadvantaged, Grant programs – social programs, Head Start, Health care, Mask use, Monitoring, Safety, Vaccination,

_____

JooYeun Chang,

Principal Deputy Assistant Secretary for

Children and Families.

Approved:

_____

Xavier Becerra,

Secretary.

For the reasons discussed in the preamble, we amend 45 CFR part 1302 as follows:

PART 1302 - PROGRAM OPERATIONS

1. The authority citation for part 1302 continues to read as:

Authority: 42 U.S.C. 9801 et seq.

2. In §1302.47, revise paragraphs (b)(5)(iv) and (v) and add paragraph (b)(5)(vi) to read as follows:

§ 1302.47. Safety practices.

* * * * *

(b) * * *

(5) * * *

(iv) Only releasing children to an authorized adult;

(v) All standards of conduct described in § 1302.90(c); and

(vi) Masking, using masks recommended by CDC, for all individuals 2 years of age or older when there are two or more individuals on a vehicle owned, leased, or arranged by the Head Start program; indoors in a setting when Head Start services are provided; and for those not fully vaccinated, outdoors in crowded settings or during activities that involve sustained close contact with other people, except:

(A) Children or adults when they are either eating or drinking;

(B) Children when they are napping;

(C) When a person cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act; or

(D) When a child's health care provider advises an alternative face covering to accommodate the child's special health care needs.

* * * * *

3. In § 1302.93, add paragraphs (a)(1) and (2) to read as follows:

Subpart I – Human Resources Management

§ 1302.93. Staff health and wellness.

(a) * * *

(1) All staff, and those contractors whose activities involve contact with or providing direct services to children and families, must be fully vaccinated for COVID-19, other than those employees:

(i) For whom a vaccine is medically contraindicated;

(ii) For whom medical necessity requires a delay in vaccination; or

(iii) Who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirements based on an applicable Federal law.

(2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS-COV-2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or working directly with children. Those with positive test results must be immediately excluded from the facility, so they are away from children and staff until they are determined to no longer be infectious.

* * * * *

4. In § 1302.94, revise paragraph (a) to read as follows:

§ 1302.94 Volunteers.

(a) A program must ensure volunteers have been screened for appropriate communicable diseases in accordance with state, tribal or local laws. In the absence of state, tribal, or local law, the Health Services Advisory Committee must be consulted regarding the need for such screenings.

(1) All volunteers in classrooms or working directly with children other than their own must be fully vaccinated for COVID-19, other than those volunteers:

(i) For whom a vaccine is medically contraindicated;

(ii) For whom medical necessity requires a delay in vaccination; or

(iii) Who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirements based on an applicable Federal law.

(2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS-CoV-2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or work directly with children. Those with positive test results must be immediately excluded from the facility, so they are away from children and staff until they are determined to no longer be infectious.

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